(A) better trained public health professionals and epidemiologists to recognize epidemic patterns;

(B) appropriate laboratory equipment for diagnosis of pathogens; and

(C) appropriate communications to efficiently transmit information and data within national and regional health networks.

(8) An effective international capability to monitor and quickly diagnose infectious disease epidemics will offer dividends not only in the event of biological weapons development, testing, production, and attack, but also in the more likely cases of naturally occurring infectious disease epidemics.

(b) PURPOSE.—The purposes of this title are as follows:

(1) To enhance the capability of the international community, through the World Health Organization and individual countries, to detect, identify, and contain infectious disease epidemics, whether the cause of those epidemics is intentional human action or natural in origin.

(2) To enhance the training of public health professionals and epidemiologists from eligible developing countries so that they may better detect, diag-

nose, and contain infectious disease epidemics, especially those due to pathogens most likely to be used in a biological weapons attack.

(3) To provide assistance to developing countries to purchase appropriate public health laboratory equipment necessary for infectious disease surveillance and diagnosis.

(4) To provide assistance to developing countries to purchase appropriate communications equipment necessary to effectively gather, analyze, and report public health information both within countries and to the World Health Organization.

(5) To make available greater numbers of United States Government public health professionals to international health organizations, regional health networks, and United States diplomatic missions where appropriate.

(6) To establish "lab-to-lab" cooperative relationships between United States public health laboratories and distinguished foreign counterparts.

(7) To expand the training and outreach activities of overseas United States laboratories, including Centers for Disease Control and Prevention and Department of Defense entities, to enhance the public health capabilities of developing countries.

(8) To provide appropriate technical assistance to existing regional health networks and, where appropriate, seed money for new regional networks.

(9) To mandate a study to be carried out by the National Academy of Science's Institute of Medicine on the adaptability and appropriateness of modern public health technology for use in developing countries.

SEC. 603. DEFINITIONS.

In this title:

(1) ELIGIBLE DEVELOPING COUNTRY.—The term "eligible developing country" means any developing country that—

(A) has agreed to the objective of fully complying with requirements of the World Health Organization regarding reporting public health information on outbreaks of infectious diseases;

(B) is not a state sponsor of terrorism, unless the President exercises a waiver certifying that it is in the national interest of the United States to provide assistance under the provisions of this title; and

(C) is a state party to the Biological Weapons Convention.

(2) ELIGIBLE NATIONAL.—The term "eligible national" means any citizen or national of an eligible developing country who does not have a criminal background, who is not on any immigration or other United States watch list, and who is not affiliated with any foreign terrorist organization.

(3) INTERNATIONAL HEALTH ORGANIZATION.—The term "international health organization" includes the World Health Organization and the Pan American Health Organization.

(4) LABORATORY.—The term "laboratory" means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(5) SECRETARY.—Unless otherwise provided, the term "Secretary" means the Secretary of State.

SEC. 604. PRIORITY FOR CERTAIN COUNTRIES.

Priority in the provision of United States assistance for eligible developing countries under all the provisions of this title shall be given to those countries that permit

personnel from the World Health Organization and the Centers for Disease Control and Prevention to investigate fully outbreaks of infectious diseases on their territories.

SEC. 605. RESTRICTION.

Notwithstanding any other provision of this title, no foreign nationals shall have access to United States controlled select or restricted agents that may be used as, or in, a biological weapon, except in a supervised and controlled setting.

SEC. 606. FELLOWSHIP PROGRAM.

(a) ESTABLISHMENT.—There is established a fellowship program (in this section referred to as the "program") under which the Secretary shall, subject to the availability of appropriations, award fellowships to eligible nationals of eligible developing countries to pursue public health education or training, as follows:

(1) MASTER OF PUBLIC HEALTH DEGREE.—Graduate courses of study leading to a master of public health degree with a concentration in epidemiology from an institution of higher education in the United States with an Academic Center for Public Health Preparedness, as designated by the Centers for Disease Control and Prevention.

(2) ADVANCED PUBLIC HEALTH EPIDEMIOLOGY TRAINING.—Advanced public health training in epi-

demiology for public health professionals from eligible developing countries to be carried out at the Centers for Disease Control and Prevention (or equivalent State facility), or other Federal facility (excluding the Department of Defense or United States National Laboratories), for a period of not less than 6 months or more than 12 months.

(b) SPECIALIZATION IN BIOTERRORISM.—In addition to the education or training specified in subsection (a), each recipient of a fellowship under this section (in this section referred to as a "fellow") shall take courses of study at the Centers for Disease Control and Prevention or at an equivalent facility on diagnosis and containment of likely bioterrorism agents.

(c) FELLOWSHIP AGREEMENT.—

(1) IN GENERAL.—In awarding a fellowship under the program, the Secretary shall require the recipient to enter into an agreement under which, in exchange for such assistance, the recipient—

(A) will maintain satisfactory academic progress (as determined in accordance with regulations issued by the Secretary and confirmed in regularly scheduled updates to the Secretary from the institution providing the education or

training on the progress of the recipient's education or training);

(B) will, upon completion of such education or training, return to the recipient's country of nationality or last habitual residence and complete at least three years of employment in a public health position in the government or a nongovernmental, not-for-profit entity of that country or, with the approval of the Secretary and the government concerned, in an international health organization; and

(C) agrees that, if the recipient is unable to meet the requirements described in subparagraph (A) or (B), the recipient will reimburse the United States for the amount of the assistance provided to the recipient under the fellowship, together with interest at a rate determined in accordance with regulations issued by the Secretary but not higher than the rate generally applied in connection with other Federal loans.

(2) WAIVERS.—The Secretary may waive the application of paragraph (1)(B) and (1)(C) if the Secretary determines that it is in the national interest of the United States to do so.

(d) IMPLEMENTATION.—The Secretary is authorized to enter into an agreement with any eligible developing country under which the developing country agrees—

(1) to establish a procedure for the nomination of eligible nationals for fellowships under this section;

(2) to guarantee that a fellow will be offered a professional public health position within the developing country upon completion of his studies; and

(3) to certify to the Secretary when a fellow has concluded the minimum period of employment in a public health position required by the fellowship agreement, with an explanation of how the requirement was met.

(e) PARTICIPATION OF UNITED STATES CITIZENS.—On a case-by-case basis, the Secretary may provide for the participation of United States citizens under the provisions of this section if the Secretary determines that it is in the national interest of the United States to do so. Upon completion of such education or training, a United States recipient shall complete at least four years of employment in a public health position in an eligible developing country.

(f) ACCESS TO CDC PROGRAMS.—The Secretary, in consultation with the Secretary of Health and Human

Services, may offer fellowships to eligible nationals of eligible foreign countries to participate in the Field Epidemiology Training Program administered run by the Centers for Disease Control and Prevention, in lieu of participation in the fellowship program described in subsection (a). The provision described in subsections (b), (c), and (d) shall continue to apply under this subsection.

SEC. 607. IN-COUNTRY TRAINING IN MODERN LABORATORY TECHNIQUES.

In conjunction with the Centers for Disease Control and Prevention and the Department of Defense, the Secretary shall establish a program that would offer short training courses in-country (not in the United States) to laboratory technicians and other public health personnel from eligible developing countries in modern laboratory techniques relating to the identification, diagnosis, and tracking of pathogens responsible for possible infectious disease epidemics. Training under this section may be conducted in overseas facilities of the Centers for Disease Control and Prevention or in Overseas Medical Research Units of the Department of Defense, as appropriate.

SEC. 608. ASSISTANCE FOR THE PURCHASE AND MAINTENANCE OF PUBLIC HEALTH LABORATORY EQUIPMENT.

(a) AUTHORIZATION.—The President is authorized, on such terms and conditions as the President may determine, to furnish grant assistance to eligible developing countries to purchase and maintain public health laboratory equipment described in subsection (b).

(b) EQUIPMENT COVERED.—Equipment described in this subsection is equipment that is—

(1) appropriate, where possible, for use at the primary health care level in the intended geographic area;

(2) necessary to collect, analyze, and identify expeditiously a broad array of pathogens, including mutant strains, which may cause infectious disease outbreaks or may be used as a biological weapon;

(3) compatible with general standards set forth by the World Health Organization and, as appropriate, the Centers for Disease Control and Prevention, to ensure basic interoperability with regional and international public health networks; and

(4) not controlled goods, know how, or technology under the Arms Export Control Act or the Export Administration Act of 1979 (or successor statute)

(c) PROCUREMENT PREFERENCE.—In the use of grant funds authorized under subsection (a), preference shall be given to the purchase of equipment of United States manufacture.

(d) HOST COUNTRIES COMMITMENTS.—The assistance provided under this section shall be contingent upon the host country's commitment to provide the resources, infrastructure, and other assets required to house support, secure, and maximize use of this equipment.

SEC. 609. ASSISTANCE FOR IMPROVED COMMUNICATION OF PUBLIC HEALTH INFORMATION.

(a) ASSISTANCE FOR PURCHASE OF COMMUNICATION EQUIPMENT AND INFORMATION TECHNOLOGY.—The President is authorized to provide, on such terms and conditions as the President may determine, assistance to eligible developing countries for the purchase and maintenance of communications (and information technology) equipment described in subsection (b), and supporting equipment, necessary to effectively collect, analyze, and report public health information. Assistance under this subsection shall be provided in the form of grants.

(b) COVERED EQUIPMENT.—Equipment described in this subsection is equipment that—

(1) is suitable for use under the particular conditions of the area of intended use;

(2) meets appropriate World Health Organization standards to ensure interoperability with like equipment of other countries and international organizations; and

(3) is not controlled goods, know how, or technology under the Arms Export Control Act or the Export Administration Act of 1979 (or successor statutes).

(c) PROCUREMENT PREFERENCE.—In the use of grant funds under subsection (a), preference shall be given to the purchase of communications (and information technology) equipment of United States manufacture.

(d) ASSISTANCE FOR STANDARDIZATION OF REPORTING.—The President is authorized to provide, on such terms and conditions as the President may determine, technical assistance and grant assistance to international health organizations (including regional international health organizations) to facilitate standardization in the reporting of public health information between and among developing countries and international health organizations.

(e) HOST COUNTRIES COMMITMENTS.—The assistance provided under this section shall be contingent upon the host country's commitment to provide the resources,

infrastructure, and other assets required to support, secure, and maximize use of this equipment.

SEC. 610. ASSIGNMENT OF PUBLIC HEALTH PERSONNEL TO UNITED STATES MISSIONS AND INTERNATIONAL ORGANIZATIONS.

(a) IN GENERAL.—Upon the request of a United States chief of diplomatic mission or an international health organization, and with the concurrence of the Secretary of State, the head of a Federal agency may assign to the respective United States mission or organization any officer or employee of the agency occupying a public health position within the agency.

(b) REIMBURSEMENT.—The costs incurred by a Federal agency by reason of the detail of personnel under subsection (a) may be reimbursed to that agency out of the applicable appropriations account of the Department of State.

SEC. 611. LABORATORY-TO-LABORATORY EXCHANGE PROGRAM.

(a) AUTHORITY.—The President is authorized to provide by grant, contract, or otherwise for educational exchanges by financing educational activities—

(1) of United States public health personnel in approved public health laboratories in eligible developing countries; and

(2) of public health personnel of eligible developing countries in United States public health laboratories.

(b) APPROVED PUBLIC HEALTH LABORATORIES DEFINED.—In this section, the term "approved public health laboratories" means public health laboratories (other than Department of Defense and United States National laboratories) that the President determines are well-established and have a demonstrated record of excellence.

SEC. 612. EXPANSION OF CERTAIN UNITED STATES GOVERNMENT LABORATORIES ABROAD.

(a) IN GENERAL.—Subject to the availability of appropriations, the Centers for Disease Control and Prevention and the Department of Defense shall each—

(1) increase the number of personnel assigned to laboratories of the Centers or the Department, as appropriate, located in eligible developing countries that conduct research and other activities with respect to infectious diseases; and

(2) expand the operations of those laboratories, especially with respect to the implementation of on-site training of foreign nationals and activities affecting neighboring countries to the country in which the laboratory is located.

(b) COOPERATION AND COORDINATION BETWEEN LABORATORIES.—Subsection (a) shall be carried out in such a manner as to foster cooperation and avoid duplication between and among laboratories.

(c) RELATION TO CORE MISSIONS AND SECURITY.—The expansion of the operations of overseas laboratories of the Centers or the Department under this section shall not in any way—

(1) detract from the established core missions of the laboratories; or

(2) compromise the security of those laboratories, as well as their research, equipment, know how, and materials.

SEC. 613. ASSISTANCE FOR REGIONAL HEALTH NETWORKS AND IN-COUNTRY TRAINING.

The President is authorized, on such terms and conditions as the President may determine, to provide technical assistance for the purposes of—

(1) enhancing the surveillance and reporting capabilities for the World Health Organization and existing regional health networks; and

(2) developing new regional health networks.

SEC. 614. COMBINATION AND CONSOLIDATION OF EXISTING PROGRAMS WITH PROGRAMS UNDER THIS TITLE.

The Secretary may administer programs called for under this title in conjunction with existing programs on infectious disease surveillance and monitoring on the former Soviet Union where appropriate.

SEC. 615. STUDY CONCERNING THE USE OF CERTAIN EQUIPMENT IN ELIGIBLE DEVELOPING COUNTRIES.

(a) STUDY.—The Secretary of Health and Human Services, acting through a contract with the National Academy of Science's Institute of Medicine, shall conduct a study concerning the adaptability and appropriateness of public health, surveillance, monitoring, and reporting equipment and technology for use in eligible developing countries.

(b) REPORT.—Not later than December 31, 2002, the Institute of Medicine shall prepare and submit to the Secretary of Health and Human Services and the appropriate committees of Congress a report concerning the results of the study conducted under subsection (a).

SEC. 616. AUTHORIZATION OF APPROPRIATIONS.

(a) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—Subject to subsection (c), there are authorized to be appropriated $70,000,000

for the fiscal year 2002 and $80,000,000 for fiscal year 2003, to carry out this title, for the purpose of providing eligible developing countries, based on the likelihood of the occurrence of new infectious diseases or the procurement, development, testing, production, or weaponization of bioterrorism agents, with the basic means (such as trained personnel, laboratory equipment, and essential communications) to detect, diagnose, and contain such pathogens.

(2) ALLOCATION OF FUNDS.—Of the amounts made available under paragraph (1)—

(A) $50,000,000 for the fiscal year 2002 and $50,000,000 for the fiscal year 2003 are authorized to be available to carry out sections 606, 607, 608, and 609;

(B) not to exceed $4,000,000 for each of the fiscal years 2002 and 2003 for the specific training programs authorized in section 606(a)(1) and 606(f);

(C) $5,000,000 for the fiscal year 2002 and $5,000,000 for the fiscal year 2003 are authorized to be available to carry out section 610;

(D) $2,000,000 for the fiscal year 2002 and $2,000,000 for the fiscal year 2003 are authorized to be available to carry out section 611;

(E) $10,000,000 for the fiscal year 2002 and $30,000,000 for the fiscal year 2003 are authorized to be available to carry out section 612; and

(F) $3,000,000 for the fiscal year 2002 and $3,000,000 for the fiscal year 2003 are authorized to be available to carry out section 613.

(b) AVAILABILITY OF FUNDS.—The amount appropriated pursuant to subsection (a) is authorized to remain available until expended.

(c) REPORTING REQUIREMENT.—

(1) REPORT.—Not later than 90 days after the date of enactment of this Act, the Secretary shall submit a report, in conjunction with the Secretary of Health and Human Services and the Secretary of Defense, containing—

(A) a description of the implementation of programs under this title; and

(B) an estimate of the level of funding required to carry out those programs at a sufficient level.

(2) LIMITATION ON OBLIGATION OF FUNDS.—Not more than 10 percent of the amount appropriated pursuant to subsection (a) may be obligated before the date on which a report is submitted, or required to be submitted, whichever first occurs, under paragraph (1).

TITLE VII—INTERNATIONAL PARTNERSHIPS TO PREVENT BIOTERRORISM

SEC. 701. INTERNATIONAL PREVENTION.

(a) REPORT CONCERNING BIOLOGICAL WEAPONS CONVENTION.—Not later than 90 days after the date of enactment of this Act, the Secretary of State shall prepare and submit to the appropriate committees of Congress a report concerning suggested compliance protocols applicable to the Biological Weapons Convention, including protocols relating to arranged visits to closed biological weapon laboratory sites in Russia and for the conduct of further security risk assessments of all such laboratory sites.

(b) INTERNATIONAL SCIENCE AND TECHNOLOGY CENTER.—

(1) IN GENERAL.—There are authorized to be appropriated $45,000,000 for each of fiscal years 2002 through 20____, to enable the Secretary of State, acting through the International Science and Technology Center, to award research grants relating to threats posed by bioterrorism.

(2) SET-ASIDE.—Of the amount appropriate for each fiscal year under paragraph (1), the Secretary of State shall make available $10,000,000 for uses relating to biological weapon scientists and engineers.

(c) CIVILIAN RESEARCH AND DEVELOPMENT FOUNDATION.—There are authorized to be appropriated $1,500,000 for each of fiscal years 2002 through 20____, to enable the Civilian Research and Development Foundation of the National Science Foundation to award grants—

(1) to enable scientists of the former Soviet Union to attend conferences relating to employment on commercially-bound product research; and

(2) to enable such scientists to obtain business-management training with respect to commercially-bound projects.

(d) REPORT ON INTERNATIONAL EFFORTS.—Not later than December 31, 2002, and each December 31

thereafter, the Secretary of State shall prepare and submit to the appropriate committees of Congress an annual report concerning international efforts to minimize the risk of chemical and biological weapon proliferation. Such reports may be designated as classified if the Secretary determines that the public availability of any such report would expose the United States to additional risks.

SEC. 702. SUPPLEMENTAL AUTHORIZATIONS OF APPROPRIATIONS FOR FISCAL YEAR 2002 FOR CERTAIN NONPROLIFERATION PROGRAMS AND ACTIVITIES.

(a) DEPARTMENT OF STATE.—There is hereby authorized to be appropriated for the Department of State for fiscal year 2002, $8,000,000 for programs and activities to assist other nations in redirecting to civilian research and commercial purposes the biological weapons capabilities (including expertise and facilities) in such nations.

(b) COOPERATIVE THREAT REDUCTION PROGRAMS.—

(1) FUNDING.—There is authorized to be appropriated for the Department of Defense for fiscal year 2002, $10,000,000 for Cooperative Threat Reduction programs for biological weapons proliferation prevention activities in the former Soviet Union.

(2) DEFINITION.—In this subsection, the term "Cooperative Threat Reduction programs" means the programs specified in section 1501(b) of the National Defense Authorization Act for Fiscal Year 1997 (Public Law 104–201; 110 Stat. 2731; 50 U.S.C. 2362 note).

(c) INITIATIVE FOR PROLIFERATION PREVENTION PROGRAMS.—There is authorized to be appropriated for the Department of Energy for fiscal year 2002, $9,000,000 for programs under the Initiatives for Proliferation Prevention relating to biological threat reduction.

(d) SUPPLEMENT NOT SUPPLANT.—

(1) IN GENERAL.—The amounts authorized to be appropriated for fiscal year 2002 by subsections (a), (b), and (c) for the programs and activities referred to in such subsections are in addition to any other amounts authorized to be appropriated for fiscal year 2002 for such programs and activities.

(2) NO APPLICATION OF LIMITATIONS.—No limitation under any other provision of law on the obligation or expenditure of funds for programs and activities referred to in subsection (a), (b), or (c) shall apply with respect the obligation and expenditure of amounts authorized to be appropriated by

such subsection for such programs and activities for fiscal year 2002.

under section [606(e)] for eligible entities under this section.

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $20,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006.

SEC. 519. NATIONAL INVENTORY OF HAZARDOUS CHEMICAL AND BIOLOGICAL AGENTS.

(a) IN GENERAL.—The Secretary shall carry out the following activities to develop a national inventory of hazardous chemical and biological agents contained in agricultural research facilities:

(1) Develop and distribute a model inventory procedure for use by agricultural research facilities.

(2) Establish a national inventory of hazardous chemical and biological agents at agricultural research facilities and systems to ensure the secure transmission of inventory information.

(3) Conduct annual inventory maintenance activities.

(b) COORDINATION.—The inventory under subsection (a) shall be developed in coordination with, or as a component part of, similar inventory or database systems that are in existence on the date of enactment of this Act or

that are being developed by the Director of the Office of Homeland Security.

(c) LIMITATION.—A land grant university that has hazardous, chemical, or biological agents contained in the national inventory under this section shall not be eligible to receive formula funds from the Secretary of Agriculture after October 1, 2002 unless such university meets the minimum security standards established under section 517(c).

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, and there are appropriated, $2,000,000 to carry out this section.

SEC. 520. MONITORING ACCESS TO AGRICULTURAL RESEARCH FACILITIES.

(a) IN GENERAL.—The Secretary, in consultation with the Director of the Office of Homeland Security, shall establish a national protocol for the screening of individuals who require access to agricultural research facilities in a manner that provides for the protection of personal privacy.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, and there are appropriated, $2,000,000 to carry out this section.

[SEC. 521. USE OF WEAPONS OF MASS DESTRUCTION.

Section 2332a(a) of title 18, United States Code, is amended—

(1) in paragraph (2), by striking "or" at the end;

(2) in paragraph (3), by adding "or" at the end thereof; and

(3) by inserting after paragraph (3), the following:

"(4) against any private property, including food processing or manufacturing facilities, livestock and agricultural property,".]

SEC. 522. INDUSTRY-ON-FARM BIOSECURITY.

(a) EDUCATION PROGRAM.—The Secretary shall develop and implement a program to provide education relating to farms, livestock confinement operations, and livestock auction biosecurity to prevent the intentional or accidental introduction of a foreign animal disease and to attempt to discover the introduction of such a disease before it can spread into an outbreak. Biosecurity for livestock includes animal quarantine procedures, blood testing of new arrivals, farm locations, control of human movement onto farms and holding facilities, control of vermin, and movement of vehicles onto farms.

(b) QUARANTINE AND TESTING.—The Secretary shall develop animal quarantine and testing guidelines to

enable farmers and producers to better monitor new arrivals. Such guidelines shall be disseminated to farmers through a program of education to be developed and implemented by the Secretary. Any educational seminars and training carried out the Secretary relating to biosecurity issues shall emphasize the economic benefits of biosecurity and the profound negative impact of an outbreak.

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, and there are appropriated, $2,000,000 to carry out this section.

SEC. 523. BIOSECURITY OF FOOD MANUFACTURING, PROCESSING, AND DISTRIBUTION.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), in consultation with the Attorney General, may award grants, contracts, or cooperative agreements to enable food manufacturers, food processors, food distributors, and other entities regulated by the Secretary for purposes of ensuring the safety of food through the development and implementation of educational programs to ensure the security of their facilities and modes of transportation against potential bioterrorist attack.

(b) BEST PRACTICES.—The Secretary shall develop best practices to enable entities eligible for funding under

this section to secure their facilities and modes of transportation against potential bioterrorist attacks.

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $20,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006.

SEC. 524. GENERAL BIOSECURITY UPGRADES.

Out of any moneys in the Treasury not otherwise appropriated, the Secretary of the Treasury shall provide the Secretary of Agriculture $101,212,500 for Department of Agriculture biosecurity initiatives required under Presidential Directive (PDD-67), to be used to secure resources at existing facilities of the Agricultural Research Service and Animal and Plant Health Inspection Service.

Subtitle B—Protection of the Food Supply

SEC. 531. ADMINISTRATIVE DETENTION.

(a) EXPANDED AUTHORITY.—Section 304 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 334) is amended by adding at the end the following:

"(h) ADMINISTRATIVE DETENTION OF FOODS.—

"(1) AUTHORITY.—Any officer or employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any

article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or employee, if the officer or employee has credible evidence or information indicating that the article is in violation of this Act and poses a risk to human or animal health.

"(2) PERIOD OF DETENTION; APPROVAL BY SECRETARY OR SECRETARY'S DESIGNEE.—

"(A) DURATION.—An article of food may be detained under this subsection for a reasonable period, not to exceed 20 days, sufficient to enable the Secretary to institute an action under subsection (a) or section 302.

"(B) SECRETARY'S APPROVAL.—Before an article of food may be ordered detained under this subsection, the Secretary or an officer or employee designated by the Secretary must approve such order, after determining that the distribution of the food would threaten human or animal health.

"(3) SECURITY OF DETAINED ARTICLE.—A detention order under this subsection with respect to an article of food may require that the article be labeled or marked as detained, and may require that the article be removed to a secure facility. An article

subject to a detention order under this subsection shall not be moved by any person from the place at which it is ordered detained until release by the Secretary, or the expiration of the detention period applicable to such order, whichever occurs first.

"(4) APPEAL OF DETENTION ORDER.—Any person who would be entitled to claim a detained article if it were seized under subsection (a) may appeal to the Secretary the detention order under this subsection. Within 15 days after such an appeal is filed, the Secretary, after affording opportunity for an informal hearing, shall by order confirm the detention order or revoke it.

"(5) PERISHABLE FOODS.—The Secretary may provide in regulation in guidance for procedures for instituting and appealing on an expedited basis administrative detention of perishable foods.".

(b) PROHIBITED ACT.—Section 301 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following new subsection:

"(bb) The movement of an article of food in violation of an order under section 304(h), or the removal or alteration of any mark or label required by the order in order to identify the article as detained.".

SEC. 532. TAMPERING WITH CONSUMER PRODUCTS: ADMINISTRATIVE DETENTION.

Section 1365(f) of title 18, United States Code, is amended by adding at the end the following: "If an article of food is found during such an investigation and the Secretary has credible evidence or information indicating that the article is in violation of this Act and poses a risk to human or animal health, the Secretary may order the product detained for a period not to exceed 20 days. The detention order may require that the article be labeled or marked as detained, and may require that the article be removed to a secure facility. An article subject to a detention order under this subsection shall not be moved by any person from the place at which it is ordered detained until release by the Secretary, or the expiration of the detention period applicable to such order, whichever occurs first. Within 15 days after the detention, the Secretary must give public notice of the detention in a newspaper of general circulation in the district in which the detained article is located. Such notice must state the method by which, and the time in which, a party may appeal the determination to detain the article. Any person with a possessory interest in the article may appeal the determination to the United States District Court in the district in which the detained article is located. Nothing in this section shall preclude in rem proceedings under section 304 of the Fed-

eral Food, Drug and Cosmetic Act or any other proceeding available at law or in equity.''.

SEC. 533. DEBARMENT FOR REPEATED OR SERIOUS FOOD IMPORT VIOLATIONS.

(a) DEBARMENT AUTHORITY.—

(1) PERMISSIVE DEBARMENT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)(1)) is amended—

(A) by striking the period at the end of subparagraph (B) and inserting ''; or''; and

(B) by adding at the end the following:

''(C) a person from importing a food or offering a food for import into the United States if—

''(i) the person has been convicted of a felony for conduct relating to the importation into the United States of any food; or

''(ii) the person has repeatedly or deliberately imported or offered for import adulterated or misbranded food.''.

(2) CONFORMING AMENDMENT.—Section 306(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)(2)) is amended—

(A) in the paragraph heading, by inserting "RELATING TO DRUG APPLICATIONS" after "DEBARMENT"; and

(B) in the matter preceding subparagraph (A), by striking "paragraph (1)" and inserting "subparagraphs (A) and (B) of paragraph (1)".

(3) DEBARMENT PERIOD.—Section 306(c)(2)(A)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(c)(2)(A)(iii)) is amended by striking "subsection (b)(2)" and inserting "subsection (b)(1)(C) or (b)(2)".

(4) TERMINATION OF DEBARMENT.—Section 306(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(d)(3)) is amended—

(A) in subparagraph (A)(i), by striking "or (b)(2)(A)" and inserting ", or (b)(2)(A), or (b)(1)(C)";

(B) in subparagraph (A)(ii)(II), by inserting "in applicable cases," before "sufficient audits"; and

(C) in subparagraph (B), in each of clauses (i) and (ii), by inserting "or (b)(1)(C)" after "(b)(2)(B)".

(5) EFFECTIVE DATES.—Section 306(l)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(l)(2)) is amended—

(A) in the first sentence, by inserting "and subsection (b)(1)(C)" after "subsection (b)(2)(B)"; and

(B) in the second sentence, by striking "and subsections (f) and (g) of this section" and inserting "subsections (f) and (g), and subsection (b)(1)(C)".

(b) CONFORMING AMENDMENT.—Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 402) is amended by adding at the end the following:

"(h) If it is an article of food imported or offered for import into the United States by, with the assistance of, or at the direction of, a person debarred under section (b)(1)(C).".

SEC. 534. MAINTENANCE AND INSPECTION OF RECORDS FOR FOODS.

(a) IN GENERAL.—Chapter IV of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

"SEC. 414. MAINTENANCE AND INSPECTION OF RECORDS.

"(a) IN GENERAL.—If the Secretary has reason to believe that an article of food is in violation of this Act,

each person that manufactures, processes, packs, distributes, receives, holds, or imports such food shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and to copy all records that may assist the Secretary to determine the cause and scope of the violation. This requirement applies to all records relating to such manufacture, processing, packing, distribution, receipt, holding, or importation maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.

"(b) REGULATIONS CONCERNING RECORDKEEPING.—The Secretary may promulgate regulations regarding the maintenance of records by persons such as those that manufacture, process, pack, transport, distribute, receive, hold, or import food, as may be needed to allow the Secretary—

"(1) to promptly trace the source and chain of distribution of food, its components and ingredients, and its packaging to address threats of serious adverse health consequences to humans and animals; or

"(2) to determine whether food manufactured, processed, packed, or held by the person may be adulterated or misbranded under this Act.

The Secretary may impose reduced requirements under such regulations for small businesses with 50 or fewer employees.

"(c) LIMITATIONS.—Nothing in this section shall be construed—

"(1) to limit the authority of the Secretary to inspect records or to require maintenance of records under any other provision of or regulations issued under this Act;

"(2) to authorize the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), or

"(3) to alter or amend in any way section 552 of title 5 or section 1995 of title 18, United States Code.

"(d) INTERIM FINAL REGULATION.—A proposed regulation establishing record requirements under subsection

(b)(1) shall be effective upon publication pending consideration of public comment and publication of a final regulation, and it shall be considered final agency action for purposes of judicial review.".

(b) FACTORY INSPECTION.—Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) is amended—

(1) in paragraph (1), by adding after the first sentence the following: "In the case of any person that manufactures, processes, packs, transports, distributes, receives, holds, or imports foods, the inspection shall extend to all records and other information described in section 414(a), or required to be maintained pursuant to section 414(b)."; and

(2) in paragraph (2), in the matter preceding subparagraph (A), by striking "second sentence" and inserting "third sentence".

(c) PROHIBITED ACT.—Section 301 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 311) is amended—

(1) in subsection (e)—

(A) by striking "by section 412, 504, or 703" and inserting "by section 412, 414, 504, 703, or 704(a)"; and

(B) by striking "under section 412" and inserting "under section 412, 414(b)"; and

(2) in section (j), by inserting "414," after "412,".

SEC. 535. REGISTRATION OF FOOD MANUFACTURING, PROCESSING, AND HANDLING FACILITIES.

(a) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.), as amended by section 534, is further amended by adding at the end the following:

"SEC. 415. REGISTRATION OF FOOD MANUFACTURING, PROCESSING, AND HANDLING FACILITIES.

"(a) REGISTRATION.—

"(1) IN GENERAL.—Any facility engaged in manufacturing, processing, or handling food for consumption in the United States, including any facility of an importer, shall be registered with the Secretary. To obtain the registration—

"(A) for a domestic facility not described in subparagraph (B), the owner, operator, or agent in charge of the facility shall submit an application to the Secretary; and

"(B) for a facility of an importer, or for a foreign facility, the importer seeking to import the food product manufactured, processed, or

handled in the facility shall submit the application.

"(2) APPLICATION.—

"(A) IN GENERAL.—An entity (referred to in this section as the 'applicant') shall submit an application under paragraph (1) to the Secretary in such manner and containing such information as the Secretary shall prescribe.

"(B) SUBMISSION.—The applicant shall submit the application as provided for by the Secretary.

"(C) CONTENTS.—In the case of an application submitted for a foreign facility, the application shall contain, at a minimum, such information as the Secretary may require demonstrating that the facility, and the foreign nation involved, will permit inspections by duly commissioned officers or employees of the Secretary.

"(3) PROCEDURE.—Upon receipt and review of a completed application described in paragraph (1), the Secretary shall issue to the applicant a certificate of registration unless the Secretary finds that there is good cause for denial of the application. The Secretary shall promptly notify the applicant of the

denial, include in the notification a written explanation of the reasons for such denial, and provide an opportunity to present testimony or to reapply upon request.

"(4) LIST.—The Secretary shall compile and maintain an up-to-date list of facilities that are registered under this section. Such list shall not be subject to the disclosure requirements of section 552 of title 5, United States Code.

"(b) SUSPENSION OF REGISTRATION.—

"(1) BASIS.—The registration of a facility, including the facility of an importer, may be suspended immediately by the Secretary, or may be suspended after notice and an opportunity for a hearing as determined appropriate by the Secretary, for—

"(A) in the case of a foreign facility, the failure to permit access to the facility for inspection under this Act;

"(B) a violation of any provision of chapter IV, or a regulation issued under such chapter, concerning the facility, if the Secretary determines that such suspension is likely to prevent a significant risk of adverse health consequences; or

"(C) conviction of the applicant or registrant in any Federal or State court of—

"(i) any felony relating to food, whether or not the felony is based upon the acquisition, handling, or distribution of adulterated or misbranded food; or

"(ii) more than 1 violation of any law relating to food, whether or not the violation involves any fraud in connection with transactions in food.

"(2) NOTICE AND OPPORTUNITY FOR HEARING.—If the Secretary suspends the registration of a facility without advanced notice and an opportunity for a hearing, the Secretary shall immediately provide notice to a registrant upon such suspension and provide the registrant with an opportunity for a hearing within 3 days of the suspension.

"(3) REINSTATEMENT.—A registration suspended under paragraph (1) may be reinstated whenever the Secretary determines that the suspension is no longer necessary.

"(c) EXEMPTION AUTHORITY.—The Secretary may by regulation exempt types of retail establishments or farms from the requirements of subsection (a) if the Secretary determines that the registration of such facilities

is not needed for effective enforcement of chapter IV and any regulations issued under such chapter.

"(d) FACILITY.—In this section, the term 'facility' includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer), that manufactures, handles, or processes food.".

(b) ADULTERATED FOODS.—Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by adding at the end the following:

"(h) If it is a food from a facility for which an application for registration has not been submitted to the Secretary under section 415(a), for which the Secretary has denied an application for registration under section 415(a), or for which the Secretary has suspended registration under section 415(b).".

(c) EFFECTIVE DATE.—The amendment made by subsection (b) shall take effect 60 days after the date of enactment of this Act.

SEC. 536. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.

(a) PRIOR NOTICE IMPORTED FOOD SHIPMENTS.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following:

"(j) PRIOR NOTICE IMPORTED FOOD SHIPMENTS.—

"(1) IN GENERAL.—At least 4 hours before a food is imported or offered for importation into the United States, the producer, manufacturer, or shipper of the food shall provide documentation to the Secretary of the Treasury and the Secretary of Health and Human Services that—

"(A) identifies—

"(i) the food;

"(ii) the countries of origin of the food;

"(iii) the quantity to be imported; and

"(iv) the ingredients and countries of origin of the ingredients; and

"(B) includes such other information as the Secretary may require by regulation.

"(2) REFUSAL OF ADMISSION.—If documentation is not provided as required by paragraph (1) at least 4 hours before the food is imported or offered for importation, the food may be refused admission.

"(3) LIMITATION.—Nothing in this subsection shall be construed to authorize the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the

Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).".

(b) PROHIBITION OF KNOWINGLY FALSE STATEMENTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 602(B), is further amended by inserting after subsection (aa) the following:

"(bb) Knowingly making a false statement in documentation required under section 805.".

SEC. 537. AUTHORITY TO COMMISSION OTHER FEDERAL OFFICIALS TO CONDUCT INSPECTIONS.

Section 702(a) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 372(a)) is amended in the first sentence by inserting "or of other Federal Departments or agencies, notwithstanding any other provision of law restricting the use of a Department's or agency's officers, employees, or funds" after "officers and employees of the Department".

SEC. 538. GRANTS TO STATES FOR INSPECTIONS.

Chapter IX of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 910. GRANTS TO STATES FOR INSPECTIONS.

"(a) IN GENERAL.—The Secretary is authorized to make grants to States and Territories that undertake to examinations, inspections, and investigations, and related activities under section 702, the funds provided under such grants to be available only for the costs of conducting such examinations, inspections, investigations, and related activities.

"(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section for fiscal year 2002 and each succeeding fiscal year.".

SEC. 539. RULE OF CONSTRUCTION.

Nothing in this title, or an amendment made by this title, shall be construed to—

(1) provide the Food and Drug Administration with additional authority related to the regulation of meat, poultry, and egg products; or

(2) limit the authority of the Secretary of Agriculture with respect to such products.

Subtitle C—Research and Training to Enhance Food Safety and Security

SEC. 541. RESEARCH AND TRAINING AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.

Subpart 6 of title IV of the Public Health Service Act (42 U.S.C. 285f et seq.) is amended by adding at the end the following:

"SEC. 447C. FOOD SECURITY RESEARCH INITIATIVE THROUGH DIRECTOR OF NATIONAL INSTITUTES OF HEALTH.

"(a) EXPANSION, INTENSIFICATION, AND COORDINATION OF ACTIVITIES.—

"(1) IN GENERAL.—The Director of NIH, in consultation with the Joint Institute for Food Safety Research, and other agencies as appropriate, shall coordinate, expand, and intensify their programs concerning food-borne illness, including food-borne illnesses potentially associated with terrorism.

"(b) CENTERS OF EXCELLENCE.—

"(1) IN GENERAL.—The Director of NIH shall award grants and contracts to public or nonprofit private entities to pay all or part of the costs of planning, establishing, improving, and providing basic operating support for centers of excellence for

research into and training in food-borne illness, including food-borne illnesses potentially associated with terrorism.

"(2) POLICIES.—A grant or contract awarded under paragraph (1) shall be entered into an accordance with policies established by the Director of NIH.

"(3) USE OF FUNDS.—Funds awarded under this subsection may be used for—

"(A) the development of diagnostic techniques that are capable of rapidly detecting and identifying agents of food-borne illness, including food-borne illnesses that are potentially associated with terrorism; and

"(B) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public with respect to food-borne illness, including food-borne illness potentially associated with terrorism.

"(c) COORDINATION WITH OTHER INSTITUTES.—The Director of NIH shall coordinate the activities under this section with similar activities conducted by other national research institutes, centers, and agencies of the Na-

tional Institutes of Health, the Food and Drug Administration, and other agencies to the extent that such institutes, centers, and agencies have responsibilities that are related to food-borne illness, including food-borne illness potentially associated with terrorism.

[''(d) FUNDING.—The Secretary shall carry out this section using the existing resources of the Department of Health and Human Services.''.]

SEC. 542. SURVEILLANCE AND INFORMATION GRANTS AND AUTHORITIES.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317P the following:

''SEC. 317Q. FOOD SAFETY GRANTS.

''(a) IN GENERAL.—The Secretary may award food safety grants to States to expand the number of States participating in Pulsenet, the Foodborne Diseases Active Surveillance Network, and other networks to enhance Federal, State, and local food safety efforts.

''(b) USE OF FUNDS.—Funds awarded under this section shall be used by States to assist such States in meeting the costs of establishing and maintaining the food safety surveillance, technical and laboratory capacity needed to participate in Pulsenet, Foodborne Diseases Active

Surveillance Network, and other networks to enhance Federal, State, and local food safety efforts.

"(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, such sums as may be necessary for each fiscal year.

"SEC. 317R. SURVEILLANCE OF ANIMAL AND HUMAN HEALTH.

"(a) IN GENERAL.—The Secretary, through the Commissioner of the Food and Drug Administration, the Director of the Centers for Disease Control and Prevention, and the Secretary of Agriculture, shall develop and implement a plan for coordinating the surveillance for zoonotic disease and human disease.

"(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, such sums as may be necessary.

SEC. 543. INTRAMURAL AGRICULTURAL BIOTERRORISM RESEARCH AND DEVELOPMENT.

(a) IN GENERAL.—The Secretary of Agriculture, to the maximum extent practicable, shall utilize existing authorities to expand intramural Agricultural Research Service, and Cooperative State Research Education and Extension Service, programs to protect the food supply of the United States by conducting activities to—

(1) enhance the capability of the Service to respond immediately to the needs of Federal regulatory agencies involved in protecting the food and agricultural system;

(2) cooperate with university and private sector partners to maximize the impact of research and development;

(3) strengthen linkages with the intelligence community to better identify research needs and evaluate acquired materials;

(4) expand Service involvement with international organizations dealing with plant and animal disease control; and

(5) otherwise expand the capacity of the Service to protect against the threat of bioterrorism.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, and there are appropriated, $100,000,000 to carry out this section.

TITLE VI—GLOBAL PATHOGEN SURVEILLANCE AND RESPONSE

SECTION 601. SHORT TITLE.

This title may be cited as the "Global Pathogen Surveillance and Response Act of 2001".

SEC. 602. FINDINGS; PURPOSE.

(a) FINDINGS.—Congress makes the following findings:

(1) Bioterrorism poses a grave national security threat to the United States. The insidious nature of the threat, the likely delayed recognition in the event of an attack, and the underpreparedness of the domestic public health infrastructure may produce catastrophic consequences following a biological weapons attack upon the United States.

(2) An infectious pathogen engineered as a biological weapon and developed, tested, produced, or released in another country can quickly spread to the United States. Such a pathogen would be based upon or taken from naturally-occurring infectious diseases. Given the realities of international travel, trade, and migration patterns, a dangerous pathogen released anywhere in the world can spread to United States territory in a matter of days, before any effective quarantine or isolation measures can be implemented.

(3) To effectively combat bioterrorism and ensure that the United States is fully prepared to prevent, diagnose, and contain a biological weapons attack, measures to strengthen the domestic public health infrastructure and improve domestic surveil-

lance and monitoring, while absolutely essential, are not sufficient.

(4) The United States must enhance cooperation with the World Health Organization, regional health organizations, and individual countries to help detect and quickly contain infectious disease epidemics or bioterrorism agents before they can spread.

(5) The World Health Organization (WHO) has done an impressive job in monitoring infectious disease outbreaks around the world, particularly with the establishment in April 2000 of the Global Outbreak Alert and Response network.

(6) The capabilities of the World Health Organization are inherently limited in that its disease surveillance and monitoring is only as good as the data and information the World Health Organization receives from member countries. Developing countries in particular often cannot devote the necessary resources to build and maintain modern public health infrastructures.

(7) In particular, developing countries could benefit from—

"(A) a hospital or primary care facility that is a designated bioterrorism support hospital under subsection (e); and

"(B) a city, county, or other local government; and

"(2) prepares, in consultation with the Governor of the State in which the hospital is located, and submits to the Secretary, an application at such time, in such manner, and containing such information as the Secretary may require.

"(c) USE OF FUNDS.—An entity that receives a grant under subsection (a) shall use funds received under the grant for activities that shall include—

"(1) the training of health care professionals and public health personnel to enhance the ability of such personnel to recognize the symptoms and epidemiologic characteristics of exposure to a potential bioweapon;

"(2) the facilitation of rapid and accurate identification of potential bioweapons;

"(3) the coordination of medical care for individuals exposed to bioweapons; and

"(4) the facilitation and coordination of rapid communication of data generated from a bioterrorist

attack between such entity and appropriate local, State or Federal health agencies.

"(d) TECHNICAL STANDARDS.—Not later than 120 days after the date of enactment of this title, the Secretary shall develop, and publish in the Federal Register, technical standards relating to State Bioterrorism Preparedness and Response Plan, including guidelines relating to the equipment, training, treatment, and personnel that a hospital or health care provider shall have to be designated a bioterrorism support hospital under subsection (e).

"(e) BIOTERRORISM SUPPORT HOSPITALS.—

"(1) IN GENERAL.—To be designated as a bioterrorism support hospital under this subsection, an eligible entity shall—

"(A) meet such technical standards as are developed by the Secretary under subsection (d); and

"(B) provide assurances satisfactory to the Secretary that such entity shall, upon the declaration of a public health emergency under section 319—

"(i) consistent with technical standards developed by the Secretary under subsection (d), accept the transfer of patients experiencing serious communicable or in-

fectious disease from hospitals not designated as a bioterrorism support hospital that is within the geographic region served by such entity;

"(ii) have an adequate health care surge capacity to meet the needs of patients located in the geographic region served by such entity during a bioterrorist attack;

"(iii) agree to provide, upon request of the Governor of the State in which such hospital is located, medical supplies to any hospital, within such State; and

"(iv) have developed a plan for serving as a regional resource in the diagnosis, treatment or care for persons exposed to a bioweapon.

"(f) PREFERENCE.—In awarding grants under this section, the Secretary shall give preference to eligible entities serving major metropolitan areas.

"(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, [$400,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2012.".

SEC. 205. DESIGNATED STATE PUBLIC EMERGENCY ANNOUNCEMENT PLAN

Section 613(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5196b(b)) is amended—

(1) in paragraph (5), by striking "and" at the end;

(2) in paragraph (6), by striking the period and inserting "; and"; and

(3) by adding at the end the following:

"(7) include a plan for providing information to the public in a coordinated manner.".

SEC. 206. EMERGENCY WAIVER OF MEDICARE, MEDICAID, AND SCHIP REQUIREMENTS.

(a) WAIVER AUTHORITY.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1134, the following:

"SEC. 1135. AUTHORITY TO WAIVE REQUIREMENTS DURING NATIONAL EMERGENCIES.

"(a) PURPOSE.—

"(1) IN GENERAL.—The purposes of this section is to enable the Secretary to ensure to the maximum extent feasible, in any emergency area and during an emergency period—

"(A) that sufficient health care items and services are available to meet the needs of indi-

viduals in such area who are enrolled in the programs under titles XVIII, XIX, and XXI; and

"(B) that health care providers, physicians, and facilities that furnish such items and services in good faith, but that are unable to comply with one or more of the requirements described in subsection (b), may be reimbursed for the provision of such items or services and exempted from sanctions for such noncompliance.

"(2) EMERGENCY AREA; EMERGENCY PERIOD.—In this section—

"(A) an 'emergency area' is a geographical area in which—

"(i) an emergency or disaster has been declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; and

"(ii) a public health emergency has been declared by the Secretary pursuant to section 319 of the Public Health Service Act; and

"(B) an 'emergency period' is the period during which there exists—

"(i) an emergency or disaster has been declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; and

"(ii) a public health emergency has been declared by the Secretary pursuant to section 319 of the Public Health Service Act.

"(b) AUTHORITY OF THE SECRETARY.—To the extent necessary to accomplish the purposes described in subsection (a), the Secretary may, subject to the provisions of the section, temporarily waive or modify the application, with respect to health care items and services furnished in any emergency area during an emergency period, of the following requirements of this title or titles XVIII, XIX, or XXI, or any regulation thereunder:

"(1) The conditions of participation or other certification for hospitals and other health care facilities, including clinical laboratories.

"(2) Requirements that physicians and other health care professionals be licensed in the State in

which they provide such services, if they have equivalent licensing in another State.

"(3) Sanctions for failure to fully stabilize emergency patients prior to transfer.

"(4) Sanctions for physician referral of patients to entities having a financial relationship with the referring physician or his or her immediate family.

"(5) Limitations on payments for health care items or services furnished to patients enrolled in managed care plans or other restricted arrangements, by health care professionals or facilities not included under such plans or arrangements.

"(6) Pre-approval requirements, program participation requirements, or similar restrictions or preconditions on payments to individual practitioners, providers, or suppliers, or types of practitioners, providers, or suppliers, and on payment for types of health care items and services.

"(7) Deadlines and timetables for performance of required activities.

"(c) AUTHORITY FOR RETROACTIVE WAVIER.—A waiver or modification of requirements pursuant to this section may, at the discretion of the Secretary, be made retroactive to the beginning of the emergency period or

any subsequent date in such period as specified by the Secretary.

"(d) NOTIFICATION OF CONGRESS.—The Secretary shall provide advance written notice to Congress at least 2 days prior to exercising the authority provided under this section with respect to an emergency area.

"(e) REPORT.—Not later than 1 year after the end of an emergency period in an emergency area in which the Secretary has exercised the authority provided under this section, the Secretary shall submit to Congress a report concerning the approaches used to accomplish the purposes described in subsection (a) with respect to such area, including an evaluation of the success of such approaches and recommendations for improved approaches if the need for such emergency authority arises in the future.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if enacted on September 11, 2001.

TITLE III—PROTECTION OF CHILDREN

SEC. 301. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Title XXVIII of the Public Health Service Act, as added by section 101 and amended by section 201, is further amended by adding at the end the following:

"Subtitle C—Protection of Children

"SEC. 2831. PROTECTION OF CHILDREN.

"(a) NATIONAL TASK FORCE ON CHILDREN AND TERRORISM.—

"(1) ESTABLISHMENT.—The Secretary shall establish a National Task Force on Children and Terrorism (referred to in this subsection as the 'Task Force').

"(2) MEMBERSHIP.—The Task Force shall be composed of—

"(A) such Federal officials as may be appropriate to address the special needs of children; and

"(B) child health experts on infectious disease, environmental health, toxicology, and other relevant professional disciplines who shall be appointed by the Secretary.

"(3) RECOMMENDATIONS.—Not later that 60 days after the date of enactment of this title, the Task Force shall make recommendations to the Secretary concerning—

"(A) an assessment of the preparedness of the health care system of the United States to respond to bioterrorism aimed at children and youth, including the readiness of public health institutions, providers of health care, and other emergency service personnel to detect, diagnose and respond to bioterrorist attacks affecting large numbers of children and youth;

"(B) needed changes to the health care and emergency medical services systems, including recommendations on research, training of health personnel, and changes to the National Pharmaceutical Stockpile Program to include the medical needs of children; and

"(C) national, regional, and local health care and emergency medical services protocols for dealing with mass casualties of children and youth resulting from bioterrorism.

["(b) SECURING OUR SOCIAL SERVICES INFRASTRUCTURE TO SUPPORT CHILDREN AND FAMILIES.—

"(1) IN GENERAL.—The Secretary shall award grants to eligible entities to enable such entities to implement, develop, expand or increase the capacity of 2-1-1 call centers, or other universal hotlines, in order to connect the public to all available information hotlines, or call centers, developed in response to disaster and recovery efforts, as well as to connect the public to existing social services to provide needed help and support to children and families in crisis.

"(2) ELIGIBILITY.—To be eligible to receive a grant under paragraph (1), an entity shall—

"(A) be a non-profit organization working to implement, develop, expand, or increase the capacity of 2-1-1 call centers, or other universal hotlines in their State, region or locality; and

"(B) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, $10,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year. Amounts appropriated under the

preceding sentence shall remain available to carry out this section until expended.]

"SEC. 2832. STRENGTHENING RURAL COMMUNITY PREPAREDNESS FOR A BIOLOGICAL ATTACK.

"(a) IN GENERAL.—The Secretary shall review existing Federal counterterrorism efforts in light of specific characteristics which may render a rural community uniquely vulnerable to a biological terrorist attack, including distance, lack of emergency transport, hospital or laboratory capacity, lack of integration into State or Federal public health networks, workforce deficits, or other relevant conditions, and carry out activities where necessary to strengthen rural community preparedness.

"(b) REPORT.—Not later than 1 year after the date of enactment of the Bioterrorism Preparedness Act of 2001, the Secretary shall prepare and submit to the appropriate committees of Congress a report containing the results of the review conducted under subsection (a). If the Secretary determines that additional legislative authority is necessary to effectively strengthen rural community preparedness, the report shall contain the recommendation of the Secretary to that effect.".

TITLE IV—DEVELOPING NEW COUNTERMEASURES AND PROTECTING EXISTING COUNTERMEASURES AGAINST BIOTERRORISM

SEC. 401. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—Title XXVIII of the Public Health Service Act, as added by section 101 and amended by section 401, is further amended by adding at the end the following:

"Subtitle D—Developing New Countermeasures and Protecting Existing Countermeasures Against Bioterrorism

["SEC. 2841. ENHANCED CONTROL OF BIOLOGICAL AGENTS.

"(a) LIST OF BIOLOGICAL AGENTS AND TOXINS.—The Secretary shall, in consultation with the Secretary of Defense, Attorney General and such other Federal officials as may be appropriate, establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety, including its potential use in a bioterrorist attack on the civilian population.

"(b) CRITERIA.—In determining whether to include an agent or toxin on the list under subsection (a), the Secretary shall-

"(1) consider—

"(A) the effect on human health of exposure to the agent or toxin;

"(B) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;

"(C) the availability and effectiveness of vaccines and therapies to treat or prevent any illness resulting from infection by or exposure to the agent or toxin; and

"(D) any other criteria that the Secretary considers appropriate; and

"(2) consult with scientific experts representing appropriate professional groups.

"(c) PRIORITIZATION OF COUNTERMEASURES.—The Secretary shall prioritize countermeasures, including vaccines, therapies, medical devices and diagnostic tests, required to treat, prevent or identify infection by or exposure to agents and toxins, listed pursuant to subsection (a), which must be developed, produced or obtained in preparation for a bioterrorist attack or other significant disease emergency.

"(d) REGULATION OF TRANSFERS OF LISTED BIOLOGICAL AGENTS AND TOXINS.—The Secretary shall provide for—

"(1) the establishment and enforcement of safety procedures for the transfer of biological agents and toxins listed pursuant to subsection (a), including measures to ensure—

"(A) proper training and appropriate skills to handle such agents and toxins; and

"(B) proper laboratory facilities to contain and dispose of such agents and toxins;

"(2) safeguards to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose;

"(3) the establishment of procedures to protect the public in the event of a transfer or potential transfer of a biological agent or toxin in violation of the safety procedures established under paragraph (1) or the safeguards established under paragraph (2); and

"(4) appropriate availability of biological agents and toxins for research, education and other legitimate purposes.

"(e) DEFINITIONS.—For purposes of this section, the terms 'biological agent' and 'toxin' shall have the mean-

ings given such terms in section 178 of title 18, United States Code.]

"SEC. 2842. PUBLIC-PRIVATE RESEARCH AND DEVELOPMENT COORDINATION.

"(a) IN GENERAL.—The Secretary, in consultation with the Secretary of Defense, shall convene an advisory group to be composed of—

"(1) the Assistant Secretary of Defense for Health Affairs;

"(2) the Surgeon General;

"(3) the Director of the National Institutes of Health;

"(4) the Commissioner of Food and Drugs;

"(5) representatives of the pharmaceutical and biotechnology industries; and

"(6) other experts as determined appropriate by the Secretary.

"(b) DUTIES.—The advisory group shall, with respect to priority countermeasures (including vaccines, therapies, and diagnostic tests identified under section 2841(c)) to treat, identify, or prevent infection by a biological pathogen contained on the list developed under section 201(c)(1) of such Act—

"(1) assist ~~each respective Secretary~~ in the development of priorities for research relating to the

development and production of priority countermeasures;

"(2) establish a plan for the development of new priority countermeasures, new uses for approved products as priority countermeasures, and the manufacturer or distribution of priority countermeasures that would otherwise not be manufacturer or distributed;

"(3) facilitate the development or awarding of grants, contracts, or cooperative agreements necessary to ensure the development and production of priority countermeasures;

"(4) ensure the appropriate consideration of priority countermeasures under development, or awaiting approval or licensing, for fast track review under section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) and the use of formal meetings with sponsors and applicants under section 505(b) of such Act;

"(5) ensure that the plan developed under subsection (c) considers the needs of vulnerable populations, including children; and

"(6) advise and make recommendations to the Secretary concerning—

cordance with subchapter I of chapter 57 of title 5, United States Code, be eligible for travel, subsistence, and other necessary expenses incurred in carrying out the duties for which the individual was appointed, including per diem in lieu of subsistence.

"(4) LIABILITY.—For purposes of section 224(a) and the remedies described in such section, an individual appointed under paragraph (1) shall, while acting within the scope of such appointment, be considered to be an employee of the Public Health Service performing medical, surgical, dental, or related functions. Participation in training programs carried out by the Office of Emergency Preparedness or Federal personnel of the National System shall be considered within the scope of such an appointment (regardless of whether the individual receives compensation for such participation).

"(d) CRITERIA.—

"(1) IN GENERAL.—The Secretary shall by regulation establish criteria for the operation of the National System.

"(2) EDUCATION AND TRAINING OF PERSONNEL.—In carrying out paragraph (1), the Secretary shall establish criteria regarding the education and training of individuals who provide emer-

gency services through the National System. In the case of positions in the System that involve significant supervisory roles when the System is activated pursuant to subsection (b)(3)(A), the criteria shall require that individuals in such positions have completed education or training programs that have been accredited by an entity recognized by the Secretary for purposes of this paragraph.

"(3) PARTICIPATION AGREEMENTS FOR NON-FEDERAL ENTITIES.—In carrying out paragraph (1), the Secretary shall establish criteria regarding the participation of States and private entities in the National System, including criteria regarding agreements for such participation. The criteria shall include the following:

"(A) Provisions relating to the custody and use of Federal personal property by such entities, which may in the discretion of the Secretary include authorizing the custody and use of such property on a reimbursable basis to respond to emergency situations that are not public health emergencies for which the National System has been activated pursuant to subsection (b)(3)(A).

"(B) Provisions relating to circumstances in which an individual or entity has agreements with both the National System and another entity regarding the provision of emergency services by the individual. Such provisions shall address the issue of priorities among the agreements involved.

"(e) DEFINITION.—For purposes of this section, the term 'auxiliary services' includes mortuary services and veterinary services.

"(f) AUTHORIZATION OF APPROPRIATIONS.—

"(1) IN GENERAL.—For the purpose of providing for the Office of Emergency Preparedness and the National System, other than purposes for which amounts in the Public Health Emergency Fund under section 319 are available, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.

"(2) COORDINATION OF FUNDING.—The authorization of appropriations established in paragraph (1) for a fiscal year applies with respect to appropriations made from allocations under section 302(b) of the Congressional Budget Act of 1974 for the following subcommittees of the appropriations

committees of the House of Representatives and the Senate:

"(A) The subcommittees relating to the Departments of Labor, Health and Human Services, and Education.

"(B) The subcommittees relating to the Departments of Veterans Affairs and Housing and Urban Development and to independent agencies.

"(C) The subcommittees relating to the Department of Defense.

"(3) LIMITATION ON OBLIGATION OF FUNDS.—The obligation of amounts appropriated for the Office of Emergency Preparedness or the National System shall not be subject to any requirement that an operating plan be submitted to the Committee on Appropriations of the Senate and the Committee on Appropriations of the House of Representatives.

"SEC. 2814. CERTAIN EMPLOYMENT ISSUES REGARDING TEMPORARY APPOINTMENTS FOR OFFICE OF EMERGENCY PREPAREDNESS OR NATIONAL DISASTER MEDICAL SYSTEM.

"(a) TEMPORARY DISASTER-RESPONSE APPOINTEE.—For purposes of this section, the term 'tem-

porary disaster-response appointee' means an individual appointed by the Secretary under section 2813(c).

"(b) COMPENSATION FOR WORK INJURIES.—To the extent provided in regulations promulgated by the Secretary, a temporary disaster-response appointee shall be deemed an employee, and an injury sustained by such an individual while actually serving or while participating in a uncompensated training exercise related to such service shall be deemed 'in the performance of duty', for purposes of chapter 81 of title 5, United States Code, pertaining to compensation for work injuries.

"(c) EMPLOYMENT AND REEMPLOYMENT RIGHTS.—

"(1) IN GENERAL.—To the extent provided in regulations promulgated by the Secretary, service as a temporary disaster-response appointee and participation in a uncompensated training exercise related to such service shall be deemed 'service in the uniformed services' for purposes of chapter 43 of title 38, United States Code, pertaining to employment and reemployment rights of individuals who have performed service in the uniformed services.

"(2) NOTICE OF ABSENCE FROM POSITION OF EMPLOYMENT.—Preclusion of giving notice of service by disaster response necessity shall be deemed preclusion by 'military necessity' for purposes of sec-

tion 4312(b) of title 38, United States Code, pertaining to giving notice of absence from a position of employment. A determination of disaster response necessity shall be made pursuant to regulations prescribed by the Secretary, in consultation with the Secretary of Defense, and shall not be subject to judicial review.

"SEC. 2815. NATIONAL PHARMACEUTICAL STOCKPILE.

"(a) IN GENERAL.—The Secretary shall maintain a stockpile of vaccines, therapies, and medical supplies in amounts that are adequate to meet the health needs of the United States population, including vulnerable populations such as children and the elderly, in the event of a bioterrorist attack.

"(b) DEFINITION.—In this section, the term 'stockpile' means—

"(1) a physical accumulation of the material described in subsection (a); or

"(2) a contractual agreement between the Secretary and a vendor or vendors under which such vendor or vendors agree to provide to the Secretary such medical supplies as shall be described in the contract at such time as shall be specified in the contract.

"(c) PROCEDURES.—The Secretary shall ensure that adequate procedures are followed with respect to the stockpile maintained under subsection (a) for inventory management, accounting, and for the physical security of such stockpile.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, [$500,000,000] for each of the fiscal years 2002 through 2012.

"SEC. 2816. REPORT ON EFFECTIVENESS.

"Not later than 180 days after the date of enactment of this title, the Comptroller General shall prepare and submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report that describes the effectiveness, as compared to the cost, of the Civil Support Teams of the National Guard in responding to acts of bioterrorism against the civilian population.

"CHAPTER 2—IMPROVING COMMUNICATION OF INFORMATION ABOUT BIOTERRORISM

"SEC. 2821. EMERGENCY PUBLIC INFORMATION AND COMMUNICATIONS TASK FORCE.

"(a) IN GENERAL.—The Secretary shall convene an advisory committee to be known as the 'Emergency Public Information and Communication Task Force' (referred to in this section as the 'EPIC Task Force') to determine how best to communicate to the public prior to, and in the event of, an emergency to maximize the flow of information and minimize public panic.

"(b) MEMBERSHIP.—Not later than 30 days after the date of enactment of this title, the Secretary shall appoint not to exceed 15 individuals to serve on the EPIC Task Force. Such individuals shall be representative of public health experts, disaster management experts, communication experts, behavioral psychologists (experts in the psychology of human reaction to stress and disasters), and other experts determined appropriate by the Secretary.

"(c) MEETINGS.—The EPIC Task Force shall meet as needed to carry out its responsibilities under this section.

"(d) DUTIES.—The EPIC Task Force shall—

"(1) make findings and recommendations on appropriate ways in which to provide information to, and in which to communicate with, the public before, during, and after a bioterrorist attack or other emergency;

"(2) in making the findings and recommendations under paragraph (1), examine trusted communicators, liaisons with the media, communications with the general public, and hoax management; and

"(3) provide advise to the Secretary and others as needed after issuing the report under subsection (e).

"(e) REPORT.—Not later than 30 days after the date on which the members of the EPIC Task Force are appointed under subsection (b), the Task Force shall prepare and submit to the Secretary and the appropriate committees of Congress a report concerning the findings and recommendations made under subsection (d)(1).

"(f) AVAILABILITY OF REPORT.—The Secretary shall make the EPIC Task Force report available to media personnel, public information officers in State and local governments, State and local health officials, law enforcement personnel, emergency management personnel, military personnel, relevant Federal agencies and departments, ap-

propriate committees of Congress, and others that the Secretary determines appropriate.

"(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, [$10,000,000] for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2008.

"(h) SUNSET.—The EPIC Task Force shall terminate on the date that is 3 years after the date of enactment of this section.

"SEC. 2822. PREPAREDNESS AND RESPONSE PUBLIC SERVICE ANNOUNCEMENTS.

"(a) DEVELOPMENT.—The Secretary shall develop, either directly or through grants, contracts or cooperative agreements, public service announcements to inform the public of—

"(1) the actions that the public can take, and should be taking, to prepare individuals and their families for a bioterrorist event or emergency situation; and

"(2) what to do in the event that such an event occurs.

"(b) REQUIREMENTS.—In developing public service announcements under subsection (a) the Secretary shall ensure that—

"(1) such announcements are designed to maximize information flow to the public while minimizing public panic;

"(2) such announcements include information relevant to the special needs of children;

"(3) one or more announcements are developed and released within 30 days of the date of enactment of this title;

"(4) upon receipt of the recommendations of the EPIC Task Force under section 2831, such recommendations are considered in developing future announcements;

"(5) such announcements are developed in consultation with communications experts, public health experts, behavioral psychologists (experts in the psychology of human reaction to stress and disasters), the Surgeon General, and the Director of the Federal Emergency Management Agency; and

"(6) such announcements include the website address for the official Federal Government website on bioterrorism under section 2833, and any appropriate universal number for individuals to call for further information or in the case of an emergency.

"(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be nec-

essary to carry out this section for fiscal year 2002 and such sums as may be necessary for each subsequent fiscal year.

"SEC. 2823. OFFICIAL FEDERAL INTERNET SITE FOR BIOTERRORISM INFORMATION.

"(a) ESTABLISHMENT.—

"(1) IN GENERAL.—Not later than 180 days after the date of enactment of this title, the Secretary shall establish and maintain the official Federal Internet site containing comprehensive information relating to preparing for and responding to acts of bioterrorism.

"(2) AUTHORITY TO AWARD GRANT.—In carrying out paragraph (1), the Secretary may award a grant or cooperative agreement to an eligible entity under subsection (c).

"(b) PURPOSE.—The purpose of the website referred to in subsection (a) is to create an integrated website that serves as the official Federal Government source of information for the public and targeted populations containing accurate, scientifically-based information about bioterrorism.

"(c) ELIGIBLE ENTITY.—An eligible entity under this subsection is an entity that has demonstrated expertise in—

"(1) bioterrorism and public health;

"(2) development of websites and distribution of information; and

"(3) working with Federal Government agencies.

"(d) CONTENT.—The website referred to in subsection (a) shall contain scientifically-based information regarding—

"(1) bioterrorism and the medical consequences of exposure to bioweapons, both for human and animal health;

"(2) what the public can do to respond to a bioterrorist attack, including strategies for effective communication to children, within families and communities, about the risks of bioterrorism and how parents can talk to their children;

"(3) treatments and vaccines available to the public against pathogens that may be used in a bioterrorist attack; and

"(4) other situations or consequences of bioterrorism, or any other information, that the entity, with the approval of the Secretary or designee, determines should be included.

"(e) ORGANIZATION.—The website referred to in subsection (a) shall contain targeted sections with specific in-

formation for health care professionals, agricultural workers, and the general public.

"(f) USE OF FUNDS.—An eligible entity that receives a grant or cooperative agreement under this section shall, in consultation with public and private entities in the gathering of essential information regarding bioterrorism, and any other experts who may provide pertinent information regarding bioterrorism, use funds under the grant or agreement to develop, update, and maintain the website on bioterrorism under this section.

"(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, such sums as may be necessary for each fiscal years 2002 through 2006.".

SEC. 202. BEST PRACTICES.

(a) COUNTERMEASURES.—Section 319F(c)(3) of the Public Health Service Act (42 U.S.C. 247d-6(c)(3)) is amended by inserting "to develop best practices for dealing with a public health emergency" after "subsection (b)".

(b) DEMONSTRATION PROGRAM.—Section 319G(a) of the Public Health Service Act (42 U.S.C. 247d-7(a)) is amended by inserting "to develop best practices" after "carry out demonstration programs".

SEC. 203. TRAINING FOR PEDIATRIC ISSUES SURROUNDING BIOLOGICAL AGENTS USED IN WARFARE AND TERRORISM.

Section 319F(f) of the Public Health Service Act (42 U.S.C. 247d-6(f)) is amended by striking paragraph (2) and inserting the following:

"(2) the development of educational programs for health care professionals, recognizing the special needs of children and other vulnerable populations;".

SEC. 204. EXPANSION OF EXISTING FEDERAL BIOTERRORISM PROVISIONS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended—

(1) by redesignating sections 319A, 319B, 319C, 319D, 319E, 319F, and 319G as sections 319B, 319H, 319J, 319K, 319L, and 319N, respectively;

(2) by inserting after section 319, the following:

"SEC. 319A. STATE BIOTERRORISM PREPAREDNESS AND RESPONSE BLOCK GRANT.

"(a) IN GENERAL.—The Secretary shall award block grants to States to enable such States to prepare for and respond to bioterrorism. In administering the block grant program under this section, the Secretary shall coordinate such program with the block grant administered under the Bioterrorism Preparedness and Response Initiative.

"(b) ELIGIBILITY.—To be eligible to receive a block grant under subsection (a), a State shall—

"(1) prepare and submit to the Secretary a State Bioterrorism Preparedness and Response Plan in accordance with subsection (c); and

"(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including an assurance that—

"(A) the State will establish an advisory committee in accordance with subsection (d);

"(B) the State will use amounts received under the grant in accordance with the State plan submitted under subsection (c), including making expenditures to carry out the strategy contained in the plan;

"(C) the State will maintain State expenditures for bioterrorism activities at a level that is not less than the average level of such expenditures maintained by the State for such activities the 2-year period preceding the fiscal year for which the State is applying to receive the grant;

"(D) during the development of the State plan under subsection (c)—

"(i) the chief health officer of the State has held public forums concerning the plan or any revisions to the plan; and

"(ii) the advisory committee established under subsection (d) has been provided with an opportunity to review relevant State public health and safety information in the course of its deliberations;

"(E) the State will consult with relevant emergency response personnel, health care providers, Federal, State and local governmental agencies (including highway safety and agriculture agencies), law enforcement personnel, and relevant private organizations during the development of the State bioterrorism initiative under the grant; and

"(F) with respect to the State plan under subsection (c), the State will establish reasonable criteria to evaluate the effective performance of entities that receive funds under the grant and shall include relevant benchmarks in the State plan.

"(c) STATE BIOTERRORISM PREPAREDNESS AND RESPONSE PLAN.—Not later than 180 days after receiving amounts under a grant under this section, and annually

thereafter, a State shall prepare and submit to the Secretary a State Bioterrorism Preparedness and Response Plan for responding to biological attacks. Recognizing the assessment of public health capacity conducted under section 319H, such plan shall include—

"(1) a description of the general goals and needs of the State relating to bioterrorism;

"(2) a description of the process the State has implemented in order to identify, detect, monitor, and respond to bioterrorism, including a description of the amount expended by the State for such purposes;

"(3) a description of the programs, projects, and activities that the State will implement using amounts received under the grant in order to detect and respond to bioterrorism, including the manner in which the State will manage State surveillance and response efforts and coordinate such efforts with national efforts;

"(4) a description of the activities that the State has conducted to build local infrastructures for the prevention, detection, and response to biological attacks;

"(5) a description of the training initiatives that the State has carried out with respect to local

emergency personnel, law enforcement officials, and health care providers (including mental health professionals) relating, as appropriate, to the detection of and response to a biological attack;

"(6) a description of the cleanup and contamination prevention efforts to be implemented in the event of a biological attack in the State;

"(7) a description of the State mechanisms in place for improving the health care infrastructure in the State through the improvement of workforce capacity and competency, information and data systems, and up to date health departments and local laboratories;

"(8) a description of State efforts to ensure that hospitals and health care providers have procedures (which may include procedures for the distribution of materials from the National Pharmaceutical Stockpile) in place to provide health care items and services (including antidotes, vaccines, or other drugs or biologicals) to state residents in the event of a biological attack;

"(9) an estimate of the number and type of public health personnel needed to achieve the goals of the State and to carry out the activities included in the plan;

"(10) plans to provide appropriate health care (which may include telehealth) during and after a biological attack;

"(11) a description of the State process for gathering public input on the State plan;

"(12) a description of the manner in which the State will coordinate bioterrorism response efforts with national efforts; and

"(13) other information the Secretary may by regulation require.

"(d) STATE BIOTERRORISM PREPAREDNESS AND RESPONSE ADVISORY COMMITTEE.—

"(1) IN GENERAL.—For purposes of subsection (b)(2)(A), an advisory committee, including an existing State preparedness or hazards committee, is in accordance with this subsection if such committee is known as the State Bioterrorism Preparedness and Response Advisory Committee (in this subsection referred to as the 'Committee') and the Committee meets the conditions and performs the functions described in this subsection.

"(2) DUTIES.—A condition under paragraph (1) for a State is that the duties of the Committee are—

"(A) to hold public forums on the State plan required in subsection (b)(1); and

"(B) to make recommendations pursuant to subsection (b)(2)(D) regarding the development and implementation of such plan.

"(3) COMPOSITION.—A condition under paragraph (1) for a State is that the Committee is composed of such members of the general public, and such officials of the health departments of political subdivisions of the State, as may be necessary to provide adequate representation of the general public and of such health departments, laboratories, emergency response personnel, and agricultural stakeholders.

"(4) PROVISION RELATING TO STAKEHOLDERS.—The requirements of paragraph (3) and subsection (c) relating to public and private stakeholders shall not apply with respect to the initial State plan under subsection (c).

"(e) USE OF FUNDS.—

"(1) IN GENERAL.—Recognizing the activities conducted under sections 319H and 319I, a State shall use amounts received under a grant under this section to carry out the State plan under subsection (c). Additionally, a State may use such funds to—

"(A) prepare for a biological attack;

"(B) carry out surveillance and detection activities relating to biological attacks;

"(C) carry out activities to improve communications and coordination efforts within the State and between the State and the Federal Government, including activities to improve public health information technology, including the development of sophisticated, electronic disease surveillance systems, interoperable networks and data protocols, information exchange, and immediate access to medical data, treatment guidelines, and health alerts;

"(D) carry out activities to improve emergency response capabilities in the State;

"(E) train personnel in State and local agencies in the procedures for monitoring for, and responding to a biological attack;

"(F) establish essential epidemiologic expertise in the State through workforce improvement;

"(G) plan for triage and transport management in the event of a biological attack, including medical facilities, law enforcement,

emergency responders, and transportation officials;

"(H) strengthen communication between local medical centers, crisis management centers, and State and local health departments, including the purchase of back-up communications mechanisms (such as radios in addition to phones and electronic communications) to be used to contact local emergency response personnel during a crisis;

"(I) meet the special needs of children during and after a biological attack;

"(J) enhance the training of mental health professionals to provide effective assistance after a biological attack; and

"(K) improve the ability of hospitals and other health care facilities to provide effective health care during and after a biological attack; and

"(L) enhance the health care surge capacity of hospitals and other health care facilities.

"(2) PROHIBITED USES.—A State may not use amounts received under a grant under this section to—

"(A) provide inpatient services;

"(B) make cash payments to intended recipients of health services;

"(C) purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment; or

"(D) satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds.

"(3) WAIVER.—The Secretary may waive the limitation contained in paragraph (2)(C) upon the request of a State if the Secretary finds that there are extraordinary circumstances to justify the waiver and that granting the waiver will assist in carrying out this section.

"(f) AMOUNT OF GRANT.—

"(1) IN GENERAL.—Except as provided in paragraph (2), the amount of a grant to a State under this section for a fiscal year shall be an amount that bears the same ratio to the amount appropriated under subsection (j) for such fiscal year (and remaining after amounts are made available under paragraphs (3) and (4)) as the total population of the State bears to the total population of all States.

"(2) EXCEPTIONS.—

"(A) MINIMUM AMOUNT.—Notwithstanding paragraph (1) and subject to the extent of amounts made available under subsection (j), a State may not receive a grant under this section for a fiscal year in an amount that is less that $5,000,000.

"(B) EXTRAORDINARY CIRCUMSTANCES.—Notwithstanding paragraph (1) and subject to the extent of amounts made available under subsection (j), the Secretary may provide additional funds to a State under a grant under this section if the Secretary determines that extraordinary circumstances exist.

[

"(3) DISTRICT OF COLUMBIA AND TERRITORIES.—

"(A) IN GENERAL.—Of the amount appropriated for each fiscal year under subsection (j), there shall be reserved $35,000,000 to be provided to the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the United States Virgin Islands, and the Republic of Palua.

"(B) AMOUNT.—The amount of a grant to the District or territory described in paragraph (1) shall be an amount that bears the same

ratio to the amount available under such subparagraph for such fiscal year as the total population of the District or Territory bears to the total population of the District and all such territories.]

"(4) USE OF AVAILABLE FUNDS.—To the extent that all the funds appropriated under subsection (j) for a fiscal year and available for grants in such fiscal year are not otherwise paid to States because—

"(A) one or more States have not submitted an application or State public health disaster plan in accordance with subsections (b) and (c) for the fiscal year;

"(B) one or more States have notified the Secretary that they do not intend to use the full amount of their grant; or

"(C) some State grants are offset or repaid;

such excess shall be provided to each of the remaining States in proportion to the amount otherwise provided to such States under this subsection for the fiscal year without regard to this paragraph.

"(5) AVAILABILITY OF FUNDS.—Any amount paid to a State for a fiscal year under this sub-

section and remaining unobligated at the end of such year shall remain available for the next fiscal year to such State for the purposes for which it was made.

"(g) INDIAN TRIBES.—

"(1) IN GENERAL.—If the Secretary—

"(A) receives a request from the governing body of an Indian tribe or tribal organization within any State that funds under this section be provided directly by the Secretary to such tribe or organization; and

"(B) determines that the members of such tribe or tribal organization would be better served by means of grants made directly by the Secretary under this section;

the Secretary shall reserve from amounts which would otherwise be provided to such State under the grant for the fiscal year the amount determined under paragraph (2).

"(2) AMOUNT.—The Secretary shall reserve for the purpose of paragraph (1) from amounts that would otherwise be paid to such State under a grant under subsection (a) an amount equal to the amount which bears the same ratio to the State's grant for the fiscal year involved as the population of the In-

dian tribe or the individuals represented by the tribal organization bears to the total population of the State.

"(3) GRANT.—The amount reserved by the Secretary on the basis of a determination under this subsection shall be granted to the Indian tribe or tribal organization serving the individuals for whom such a determination has been made.

"(4) PLAN.—In order for an Indian tribe or tribal organization to be eligible for a grant for a fiscal year under this subsection, it shall submit to the Secretary a plan for such fiscal year which meets such criteria as the Secretary may prescribe.

"(5) DEFINITIONS.—In this subsection, the terms 'Indian tribe' and 'tribal organization' have the same meaning given such terms in section 4(b) and section 4(c) of the Indian Self-Determination and Education Assistance Act.

"(h) WITHHOLDING.—

"(1) REQUIREMENTS.—

"(A) IN GENERAL.—The Secretary shall, after adequate notice and an opportunity for a hearing conducted within the affected State, withhold or recoup funds from any State which does not use amounts received under a grant in

accordance with the requirements of this section. The Secretary shall withhold or recoup such funds until the Secretary finds that the reason for the withholding or recoupment has been removed and there is reasonable assurance that it will not recur.

"(B) INVESTIGATION.—The Secretary may not institute proceedings to withhold or recoup funds under subparagraph (A) unless the Secretary has conducted an investigation concerning whether the State has used grant amounts in accordance with the requirements of this section. Investigations required by this subparagraph shall be conducted within the affected State by qualified investigators.

"(C) RESPONSE TO COMPLAINTS.—The Secretary shall respond in an expeditious manner to complaints of a substantial or serious nature that a State has failed to use funds in accordance with the requirements of this section.

"(D) MINOR FAILURES.—The Secretary may not withhold or recoup funds under subparagraph (A) from a State for a minor failure to comply with the requirements of this section.

"(2) AVAILABILITY OF INFORMATION FOR INSPECTION.—Each State, and each entity which has received funds under this section, shall make appropriate books, documents, papers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the premises of the appropriate entity upon a reasonable request therefore.

"(3) LIMITATION ON REQUESTS FOR INFORMATION.—

"(A) IN GENERAL.—In conducting any investigation in a State, the Secretary or the Comptroller General of the United States may not make a request for any information not readily available to such State or an entity which has received funds under this section or make an unreasonable request for information to be compiled, collected, or transmitted in any form not readily available.

"(B) JUDICIAL PROCEEDINGS.—Subparagraph (A) does not apply to the collection, compilation, or transmittal of data in the course of a judicial proceeding.

"(i) ANNUAL REPORTS.—Not later than January 1, 2003, and annually thereafter, the General Accounting Office shall prepare and submit to the appropriate committees of Congress, a report concerning the implementation of this section. Such report shall include—

"(1) an assessment of the progress made by States in preparing for and being able to respond to a biological attack; and

"(2) recommendations for areas in which the States can improve their preparation for, or ability to respond to, a biological attack.

"(j) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriates, and there are appropriated, [$1,500,000,000 for each of fiscal years 2002 through 2006."; and

(3) by inserting after section 319B (as so redesignated), the following:

"SEC. 319C. ASSESSMENT OF PUBLIC HEALTH NEEDS.

"(a) PROGRAM AUTHORIZED.—Not later than 1 year after the date of the enactment of this title and every 10 years thereafter, the Secretary shall award grants to States, or consortia of two or more States or political subdivisions of States, to perform, in collaboration with local public health agencies, an evaluation to determine the extent to which the States or local public health agencies

can achieve the capacities applicable to State and local public health agencies described in section 319B. The Secretary shall provide technical assistance to States, or consortia of two or more States or political subdivisions of States, in addition to awarding such grants.

"(b) PROCEDURE.—

"(1) IN GENERAL.—A State, or a consortium of two or more States or political subdivisions of States, may contract with an outside entity to perform the evaluation described in subsection (a).

"(2) METHODS.—To the extent practicable, the evaluation described in subsection (a) shall be completed by using methods, to be developed by the Secretary in collaboration with State and local health officials, that facilitate the comparison of evaluations conducted by a State to those conducted by other States receiving funds under this section.

"(c) REPORT.—Not later than 1 year after the date on which a State, or a consortium of two or more States or political subdivisions of States, receives a grant under this subsection, such State, or a consortium of two or more States or political subdivisions of States, shall prepare and submit to the Secretary a report describing the results of the evaluation described in subsection (a) with respect to

such State, or consortia of two or more States or political subdivisions of States.

"(d) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section [$50,000,000] for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year through 2005.

"SEC. 319D. GRANTS TO IMPROVE STATE AND LOCAL PUBLIC HEALTH AGENCIES.

"(a) PROGRAM AUTHORIZED.—The Secretary shall award competitive grants to eligible entities to address core public health capacity needs using the capacities developed under 319B, with a particular focus on building capacity to identify, detect, monitor, and respond to threats to the public health.

"(b) ELIGIBLE ENTITIES.—A State or political subdivision of a State, or a consortium of two or more States or political subdivisions of States, that has completed an evaluation under section 319C(a), or an evaluation that is substantially equivalent as determined by the Secretary

under section 2846(a), shall be eligible for grants under subsection (a).

"(c) USE OF FUNDS.—An eligible entity that receives a grant under subsection (a), may use funds received under such grant to—

"(1) train public health personnel, including mental health professionals;

"(2) develop, enhance, coordinate, or improve participation in an electronic network by which disease detection and public health related information can be rapidly shared among national, regional, State, and local public health agencies and health care providers and the public;

"(3) develop a plan for responding to public health emergencies, including significant outbreaks of infectious diseases or bioterrorism attacks, which is coordinated with the capacities of applicable national, State, and local health agencies, health care professionals and providers, emergency response personnel, and the public, including plans for ensuring adequate hospital preparedness and specifications to address the special health needs of vulnerable populations (including children); and

"(4) enhance laboratory capacity and facilities.

"(d) REPORT.—Not later than January 1, 2005, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Commerce and the Committee on Appropriations of the House of Representatives a report that describes the activities carried out under section 2846.

"(e) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section [$950,000,000] for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year through 2007.

"SEC. 319E. EXPANSION OF EXISTING ENTITIES.

"There is authorized to be appropriated [$400,000,000] for fiscal year 2002 to expand, enhance, and improve the capabilities of the Centers for Disease Control and Prevention relating to bioterrorism preparedness. Activities that may be supported using amounts appropriated under the preceding sentence may include—

"(1) expanding or enhancing the training of personnel;

"(2) improving communications facilities related to bioterrorism;

"(3) improving laboratory facilities related to bioterrorism, including increasing the security of such facilities; and

"(4) such other activities as the Secretary determines appropriate.

"SEC. 319F. IMPROVING PUBLIC HEALTH LABORATORY CAPACITY.

"(a) IN GENERAL.—The Secretary shall provide for the establishment of a coordinated network of public health laboratories, including laboratories that serve as regional reference laboratories.

"(b) AUTHORITY.—The Secretary may award grants or cooperative agreements to eligible entities to carry out subsection (a).

"(c) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a) an entity shall—

"(1) be—

"(A) a department of public health or consortia thereof;

"(B) a State or consortia thereof; or

"(C) a political subdivision of a State or a consortia thereof; and

"(2) submit to the Secretary an application containing such information and at such time as the Secretary may require.

"(d) COORDINATION.—To the maximum extent practicable, the Secretary shall ensure that activities conducted under subsection (a) are coordinated with existing laboratory preparedness activities.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, [$100,000,000] for each of the fiscal years 2002 through 2007.

"SEC. 319G. DESIGNATED BIOTERRORISM SUPPORT HOSPITALS.

"(a) GRANTS.—The Secretary shall award project grants to eligible entities to enable such entities, in a manner consistent with applicable provisions of the State Bioterrorism Preparedness and Response Plan, to provide training, give treatment (where appropriate), purchase equipment, and train personnel to improve the diagnosis and treatment of patients exposed to infectious or communicable biological agents.

"(b) ELIGIBILITY.—To be eligible for a grant under subsection (a), an entity shall—

"(1) be a consortium that consists of at least one entity from each of the following categories—

"(A) the list of agents and toxins under section 2841(a); and

"(B) preparation of the report under section 2841(c) relating to the prioritization of countermeasures, including vaccines, therapies, and diagnostic tests, that must be developed, produced or obtained in preparation for a bioterrorist attack or other significant disease emergency.

[**"(c) PEDIATRIC STUDIES OF COUNTERMEASURES.—**

"(1) DEVELOPMENT OF LIST.—Not later than 1 year after the date of enactment of this title, and annually thereafter, the Secretary shall develop and maintain a secure and confidential list of drugs and biologics, including vaccines, that may be appropriate to prevent and treat illnesses and injury in children caused by biological pathogens of potential use in acts of warfare or bioterrorist attack.

"(2) TESTING PLAN.—Not later than 1 year after the date of enactment of this section, and annually thereafter, the Secretary shall develop a plan to provide for the timely and ethnically appropriate pediatric testing and labeling of the agents on the

list developed under subsection (a) for the year involved.

"(3) CONTRACTS.—The Secretary may award contracts to entities that have the expertise to conduct pediatric clinical trials (including qualified universities, hospitals, laboratories, contract research organizations, federally funded programs such as pediatric pharmacology research units, other public or private institutions or, individuals) to enable such entities to conduct pediatric studies concerning drugs and biologics, including vaccines, that are used to prevent and treat illnesses and injuries caused by biological agents used in acts of warfare or terrorism.

"(4) RULE OF CONSTRUCTION.—Nothing in the subsection shall be construed to alter or amend in any way section 301(j) of the Federal Food, Drug, and Cosmetic Act, section 552 of title 5, United States Code, or section 1995 of title 18, United States Code.

"(5) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, $20,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year. Amounts appropriated under the

preceding sentence shall remain available to carry out this section until expended.]

"(d) LIMITED ANTITRUST EXEMPTION.—

"(1) IN GENERAL.—Except as provided in paragraph (2), the antitrust laws shall not apply to conduct that is engaged in (including consultation and making or implementing an agreement) solely for the purpose of, and limited to, assuring the development and production of countermeasures that are prioritized under section 2841(c), consistent with the purposes of this title. This subsection shall only apply to conduct that occurs under the direction of the Secretary, or under an agreement that is made and implemented pursuant to paragraphs (2) and (3) of subsection (b) as authorized by the Secretary, after the date of enactment of this title.

"(2) EXCEPTION.—Paragraph (1) shall not apply with respect to conduct that involves or results in an agreement to boycott any person, to allocate a market, or to fix prices.

"(3) DETERMINATION.—Nothing contained in the antitrust laws shall be construed to preclude the existence and operation of any contract or agreement, or any amendments or modification of such contracts or agreements, made before or after the

date of enactment of this title, for the research, development, or purchase of countermeasures prioritized under section 2841(c), nor shall the contracting parties under such contracts or agreements be held or construed to be part of combinations or conspiracies in restraint of trade or otherwise held liable under the antitrust laws, if the Attorney General, in consultation with the Chairperson of the Federal Trade Commission and the Secretary, determines that such contract or agreement would facilitate the availability of such countermeasures.

"(e) CONSULTATION.—The Secretary shall carry out this section in consultation with the pharmaceutical, biotechnology, and medical device industries, and other appropriate experts.

"SEC. 2843. SMALLPOX AND OTHER VACCINE DEVELOPMENT,

"(a) IN GENERAL.—The Secretary shall award grants, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile described in section 2818(a) shall include the number of doses of vaccine against smallpox and other such vaccines determined by the Secretary to be sufficient to meet the needs of the population of the United States.

"(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, [$500,000,000] for each of the fiscal years 2002 through 2012.

"SEC. 2844. CONTRACT AUTHORITY FOR PRIORITY COUNTERMEASURES.

"(a) IN GENERAL.—The Secretary shall, to the extent the Secretary determines necessary to achieve the purposes of this title, enter into long-term contracts and comparable grants or cooperative agreements, for the purpose of—

"(1) ensuring the development of priority countermeasures (including vaccines, therapies, and diagnostic tests) identified under section 2841(c) to treat, identify, or prevent infection by a biological pathogen that is contained on the list developed under section 201(c)(1) of such Act, that are necessary to prepare for a bioterrorist attack or other significant disease emergency;

"(2) securing the manufacture, distribution, and adequate supply of such countermeasures;

"(3) maintaining the National Pharmaceutical Stockpile; and

"(4) carrying out such other activities determined appropriate by the Secretary to achieve the purposes of this title.

"(b) TERMS OF CONTRACTS.—Notwithstanding any other provision of law, the Secretary may enter into a contract, grant, or cooperative agreement under subsection (a) prior to the development, approval, or clearance of the countermeasure that is the subject of the contract. The contract, grant, or agreement may provide for its termination for the convenience of the Federal Government if the contractor does not develop the countermeasure involved. Such a contract, grant, or agreement may—

"(1) involve one or more aspects of the development, manufacture, or distribution of one or more countermeasure; and

"(2) set forth guaranteed minimum quantities of products and negotiated unit prices.

"SEC. 2845. HIGH QUALITY PRODUCTION OF PRIORITY COUNTERMEASURES.

"(a) IN GENERAL.—If the Secretary determines that—

"(1) a drug, biological product, or medical device that is approved, licensed, or cleared (or awaiting approval, licensure or clearance) under section 505, 510, 512, or 515 of the Federal Food, Drug,

and Cosmetic Act, or section 351 of this Act, is a priority countermeasure identified under section 2841(c) to treat, identify, or prevent infection by a biological pathogen that is contained on the list developed under section 201(c)(1) of such Act; and

"(2) compliance with good manufacturing practice regulations under sections 210, 211, 225, 226, 600, 601, 606, or 820 of title 21, Code of Federal Regulations, in the manufacturing, processing, packing, or holding for the drug, biological product, or medical device is not, in the sole judgment of the Secretary, adequate to allow its approval, licensure, or continued marketing;

the Secretary, acting through the Commissioner of Food and Drugs, may, with the agreement of the manufacturer, provide intensive assistance, including on-site assistant when necessary, to facilitate the prompt compliance with such regulations.

"(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, [$2,000,000] for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 206.

"SEC. 2846. EXPANSION AND DEVELOPMENT OF PRODUCTION FOR PRIORITY COUNTERMEASURES.

"(a) IN GENERAL.—The Secretary, in consultation with the Secretary of Defense, may award grants, contracts, or cooperative agreements for the development and expansion of the national production capacity, including novel modular production facilities, for priority countermeasure developed, or being developed, pursuant to section 2842 to treat, identify, or prevent infection by a biological pathogen.

"(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $20,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 206.

"SEC. 2847. SECURITY FOR COUNTERMEASURE RESEARCH AND PRODUCTION.

"(a) IN GENERAL.—The Secretary, in consultation with the Attorney General and the Secretary of Defense, may award grants, contracts, or cooperative agreements, and provide technical and additional nonmonetary assistance, to provide security to facilities that conduct research, development, production, distribution, and storage relating to priority countermeasures pursuant to section 2841 to treat, identify, or prevent infection by a biological pathogen.

"(b) BEST PRACTICES.—The Secretary shall develop guidelines and best practices to enable entities eligible for funding under this section to secure their facilities against potential bioterrorist attack.

"(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $10,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 206.

"SEC. 2848. ACCELERATED COUNTERMEASURE RESEARCH AND DEVELOPMENT.

"(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements for the conduct of research, investigations, experiments, demonstrations, and studies in the health sciences relating to—

"(1) the epidemiology and pathogenesis of biological pathogens of potential use is a bioterrorist attack;

"(2) the development of new vaccines and therapeutics for use against biological pathogens of potential use in a bioterrorist attack;

"(3) the development of diagnostic tests to detect biological pathogens of potential use in a bioterrorist attack; and

"(4) other relevant areas of research.

"(b) PRIORITY.—The Secretary shall prioritize the funding of research and other studies related to priority countermeasures identified pursuant to section 2841(c) to treat, identify, or prevent infection by a biological pathogen contained on the list developed under section 201(c)(1) of such Act.

"(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $15,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.".

(b) CONFORMING AMENDMENT.—Subsections (d), (e), (f), and (g) of section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 (42 U.S.C. 262 note) are repealed.

(c) EFFECTIVE DATE.—Section 2841 of the Public Health Service Act, as added by section 401(a) of this Act, shall take effect as if incorporated in the Antiterrorism and Effective Death Penalty Act of 1996.

SEC. 402. ACCELERATED APPROVAL OF PRIORITY COUNTERMEASURES.

(a) IN GENERAL.—The Secretary of Health and Human Services may designate a priority countermeasure identified pursuant to section 2841(c) of the Public Health Service Act as a fast-track product pursuant to section 506 of the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 356). Such a designation may be made prior to the submission of—

(1) a request for designation by the sponsor; or

(2) an application for the investigation of the drug under section 505(i) of such Act or section 351(a)(3) of the Public Health Service Act.

(b) USE OF ANIMAL TRIALS.—A drug approved on the basis of evidence of effectiveness that is derived from animal studies under section 403 may be designated as a fast track product for purposes of this section.

SEC. 403. USE OF ANIMAL TRIALS IN THE APPROVAL OF PRIORITY COUNTERMEASURES.

(a) NEW DRUGS.—Section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) is amended by adding at the end the following: "In the case of drugs for use against lethal or permanently disabling toxic chemical, biological, radiological, nuclear, or other substances, when adequate and well-controlled studies of effectiveness in humans cannot ethically be conducted because the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers without a proven treatment, and when adequate field trials assessing the use of the drug (in situations such as after accidental or hostile exposure to the substance) have not been feasible, the Sec-

retary may grant approval, [including approval for pediatric populations,] based on evidence of effectiveness derived from appropriate studies in animals. Appropriate post-approval studies in humans to validate such evidence of effectiveness shall be conducted whenever feasible and ethically appropriate. Drugs approved solely under the authority of the preceding two sentences shall be for purposes of treating or preventing infection, disease, injury, or other health condition or consequence resulting from a disabling toxic chemical, biological, radiological, nuclear attack, potential attack, or other significant disease emergency as the Secretary may determined appropriate, and shall only be made available for distribution pursuant to the directions of the Secretary. The Secretary may promulgate regulations establishing standards, criteria, and procedures for use of the authority provided for under the preceding three sentences.".

(b) NEW BIOLOGICAL PRODUCTS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

"(k) APPROVAL OF CERTAIN PRODUCTS BASED ON ANIMAL TRIALS.—

"(1) IN GENERAL.—In the case of biological products for use against lethal or permanently disabling toxic chemical, biological, radiological, nu-

clear, or other substances, when definitive human effectiveness studies cannot ethically be conducted because the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers without a proven treatment, and when adequate field trials assessing the use of the biological product (in situations such as after accidental or hostile exposure to the substance) have not been feasible, the Secretary may grant approval, [including approval for pediatric populations,] based on evidence of effectiveness derived from appropriate studies in animals.

"(2) POST-APPROVAL STUDIES.—With respect to a biological product approved under paragraph (1), appropriate post-approval studies in humans to validate the evidence of effectiveness shall be conducted whenever feasible and ethically appropriate.

"(3) LIMITATIONS.—Biological products approved solely under the authority of this subsection shall be for purposes of treating or preventing infection, disease, injury, or other health condition or consequence resulting from a disabling toxic chemical, biological, radiological, nuclear attack, potential attack, or other significant disease emergency as the

Secretary may determined appropriate, and shall only be made available for distribution pursuant to the directions of the Secretary.

"(4) REGULATIONS.—The Secretary may promulgate regulations establishing standards, criteria, and procedures for use of the authority provided for under this subsection.".

[SEC. 404. LIMITATION ON LIABILITY.

(a) IN GENERAL.—Section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa-14(e)) is amended by adding at the end the following:

"(3) BIOTERRORISM PRIORITY COUNTERMEASURES.—If a priority countermeasure or product is developed pursuant to section 2842 to treat, identify, or prevent infections by a biological pathogen is administered for such use by order or recommendation of the Secretary to respond to the use or threatened use of a biological agent on the list developed under section 2841(c) or upon the declaration of a public health emergency under section 319, the Secretary shall, within 60 days of such order or recommendation, amend the Vaccine Injury Table included in subsection (a) to include—

(A) such countermeasure or product,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such countermeasure or product, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such countermeasure or product may occur.".

(b) ELIGIBLE PRODUCTS.—A priority countermeasure or product developed pursuant to section 2842 of the Public Health Service Act to treat, identify, or prevent infection by biological pathogens and administered for such use by order or recommendation of the Secretary of Health and Human Services upon a declaration of a public health emergency under section 319 of such Act (42 U.S.C. 247d), shall be deemed to be a vaccine for purposes of the National Vaccine Injury Compensation Program established under section 2110 of such Act (42 U.S.C. 300aa-6).]

[SEC. 405. SECRETARY OF ENERGY.

(a) IN GENERAL.—The Secretary of Energy shall expand, enhance, and intensify research relevant to the rapid detection and identification of pathogens likely to be used in a bioterrorism attack, as described in section 2841(a).

"(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $____0,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.]

SEC. 406. MISCELLANEOUS PROVISIONS.

Title XXVIII of the Public Health Service Act, as added by section 101 and amended by section 401, is further amended by adding at the end the following:

"Subtitle E—Miscellaneous Provisions

"SEC. 2851. SUPPLEMENT NOT SUPPLANT.

"Funds appropriated under this title shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this title.

"SEC. 2852. DEFINITIONS.

"In this title:

"(1) ANTITRUST LAWS.—The term 'antitrust laws'—

"(A) has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such

section 5 applies to unfair methods of competition; and

"(B) includes any State law similar to the laws referred to in subparagraph (A).

"(2) DEVELOPMENT.—The term 'development' includes the identification of suitable compounds or biological materials, the conduct of preclinical and clinical studies, the preparation of an application for marketing approval, and any other actions related to preparation of a countermeasure.

"(3) PRIORITY COUNTERMEASURE.—The term 'priority countermeasure' means a countermeasure, including a drug, medical device, biological product, or diagnostic test, identified pursuant to section 2841(c) to treat, identify, or prevent infection by a biological pathogen on the list developed under section 2841(a).".

TITLE V—PROTECTION THE SAFETY AND SECURITY OF THE FOOD SUPPLY

SEC. 501. FINDINGS.

Congress makes the following findings:

(1) The events of September 11th have heightened awareness of the threat of intentional acts of

bioterrorism, including attacks directed at the nation's food supply and underlying agriculture.

(2) It is important to develop short, and long-term strategies and supporting technology to more effectively and efficiently protect the United States food supply from intentional acts of bioterrorism.

(3) Evidence of access to and rudimentary experiments with both chemical and biological agents and the reported interest in the operation of crop dusting aircraft point to possible terrorist intent to utilize biological weapons.

(4) Contamination of processed foods, and animal or crop disease outbreaks, whether naturally occurring or intentionally introduced, would have a profound impact on the nation's infrastructure, economy, and export markets.

(5) Enhancing current monitoring and response mechanisms to deal with a deliberate act of agricultural terrorism will strengthen our ability to quickly diagnose and respond to any animal health crisis.

(6) A program to secure and monitor supplies of hazardous chemical and biological agents is required to reduce the risk of their abuse and threat to plant and animal agriculture and the food supply.

(7) A program of ongoing research and development is required to reduce the vulnerability of both plant and animal agriculture and the food supply.

(8) Regulatory programs must expand and extend their capacities to implement new technologies in the next generation of regulatory functions.

(9) It is critical to bring Federal, State, university and private sector capacities to bear on the threat of food and agricultural bioterrorism.

Subtitle A—General Provisions to Expand and Upgrade Security

SEC. 511. FOOD SAFETY AND SECURITY STRATEGY.

(a) IN GENERAL.—The President's Council on Food Safety (as established by Executive Order 13100), shall, in consultation with the food industry, consumer producer groups, and the States, develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply. Such strategy shall address threat assessments, response and notification procedures, and risks communications to the public.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, and there are appropriated, $9,000,000 to enable the Office of Science and Technology Policy to implement the strategy developed under subsection (a) in cooperation with the Secretary of Agri-

culture, the Secretary of Health and Human Services, and the Administration of the Environmental Protection Agency.

SEC. 512. EXPANSION OF ANIMAL AND PLANT HEALTH INSPECTION SERVICE ACTIVITIES.

(a) IN GENERAL.—The Secretary of Agriculture (referred to in this section as the "Secretary") shall enhance and expand the capacity of the Animal and Plant Health Inspection Service through the conduct of activities to—

(1) increase the inspection capacity of the Service at international points of origin;

(2) improve surveillance at ports of entry and customs;

(3) enhance methods of protecting against the introduction of plant and animal disease organisms by terrorists;

(4) adopt new strategies and technologies for dealing with intentional outbreaks of plant and animal disease arising from acts of terrorism or from unintentional introduction; and

(5) otherwise expand the capacity of the Service to protect against the threat of bioterrorism.

(b) HIGH-TECH AGRICULTURE EARLY WARNING SYSTEM AND EMERGENCY RESPONSE SYSTEM.—

(1) IN GENERAL.—To provide the food and agricultural system of the United States with a new, enhanced level of protection and biosecurity that does not exist on the date of enactment of this Act, the Secretary of Agriculture shall implement a fully secure surveillance and response system that utilizes, or is capable of utilizing, field test devices capable of detecting biological threats to food, animals, and plants and that electronically integrates the devices and the tests on a real-time basis into a comprehensive surveillance, incident management, and emergency response system.

(2) EXPANSION OF SYSTEM.—The Secretary shall expand the system implemented under paragraph (1) as soon as practicable to include other Federal agencies and the States where appropriate and necessary to enhance the protection of the food and agriculture system of the United States. To facilitate the expansion of the system, the Secretary shall award grants to States.

(c) AUTOMATED RECORDKEEPING SYSTEM.—The Administrator of the Animal and Plant Health Inspection Service shall implement a central automated recordkeeping system to provide for the reliable tracking of the status of animal and plant shipments, including those

shipments on hold at ports of entry and customs. The Secretary shall ensure that such a system shall be fully accessible to or fully integrated with the Food Safety Inspection Service.

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, and there are appropriated, $185,000,000 to carry out this section.

SEC. 513. EXPANSION OF FOOD SAFETY INSPECTION SERVICE ACTIVITIES.

(a) IN GENERAL.—The Secretary shall enhance and expand the capacity of the Food Safety Inspection Service through the conduct of activities to—

(1) enhance the ability of the Service to inspect and ensure the safety and wholesomeness of meat and poultry products;

(2) improve the capacity of the Service to inspect international meat and meat products, poultry and poultry products, and egg products at points of origin and at ports of entry;

(3) strengthen the ability of the Service to collaborate with relevant agencies within the Department of Agriculture and with other entities in the Federal Government, the States, and Indian tribes through the sharing of information and technology; and